DEPARTMENT OF DEFENSE

Technology Readiness Assessment (TRA) Deskbook

September 2003

Prepared by the
Deputy Under Secretary of Defense for Science and Technology
(DUSD(S&T))

This version of the TRA Deskbook accounts for policy and guidance provided by Directive DoDD 5000.1, dated May 12, 2003; Instruction DoDI 5000.2, dated May 12, 2003; and the *Interim Defense Acquisition Guidebook*, dated October 30, 2002.

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EXECUTIVE SUMMARY

The body of this document is a concise description of suggested procedures for meeting the Technology Readiness Assessment (TRA) requirements of the Defense Acquisition System (DAS). The intent is to provide the staff of the Deputy Under Secretary of Defense for Science and Technology (DUSD(S&T)) a working appreciation of the overall TRA process, with enough detail to allow them to meet their staff responsibilities. The potential benefit to other Office of the Secretary of Defense (OSD) and Service Component participants is recognized. This deskbook should give those involved with TRAs a greater understanding of how TRAs fit into defense acquisition and what is expected by the DUSD(S&T). The DUSD(S&T) serves as the staff proponent for TRAs for the Director of Defense Research and Engineering (DDR&E).

The recently revised Department of Defense (DoD) acquisition system is documented in the following documents, each of which is available at http://dod5000.dau.mil/:

- Department of Defense Directive 5000.1, *The Defense Acquisition System,* dated May 12, 2003. This document is referred to as DoDD 5000.1. It states basic policy for defense acquisition.
- Department of Defense Instruction 5000.2, *Operation of the Defense Acquisition System,* dated May 12,. 2003. This document is referred to as DoDI 5000.2. It establishes a flexible management framework for acquisition programs and, among other things, a requirement for TRAs.
- *Interim Defense Acquisition Guidebook*, dated October 30, 2002. This document is herein referred to as *Interim Guidebook*. It provides nonmandatory guidance drawn from the earlier DoD Regulation 5000.2-R.

A central theme of the acquisition process is that the technology employed in system development should be "mature" before system development begins. Normally, for technology to be considered mature, it must have been applied in a prototype article (a system, subsystem, or component), tested in a relevant or operational environment, and found to have performed adequately for the intended application. This implies a need for a way to measure maturity and for a process to ensure that only sufficiently mature technology is employed. The *Interim Guidebook* provides an outline of a process and suggests activities for performing TRAs; however, this guidance is not mandatory. The document introduces

Technology Readiness Levels (TRLs) as an accepted way to describe technology maturity and suggests activities that could be carried out by Program Managers (PMs), Component Science and Technology (S&T) Executives, Component Acquisition Executives (CAEs), and the DUSD(S&T).

The appendixes provide extracts from relevant Government Accounting Office (GAO) and DoD reports; policy statements relevant to the TRA process; examples of TRLs and TRAs; specialized definitions and descriptions of TRLs for software and for drugs, vaccines, and medical devices; example procedures; comments on Manufacturing Readiness Levels (MRLs); and the elements of a Technology Transition Agreement. The expectation is that the basic architecture of the TRA process will remain relatively stable over time, whereas the details implementing the process will evolve and become more or less explicit over time. As changes occur, adapting the appendixes or adding new appendixes will provide an effective way for the deskbook to accommodate these changes.

I. INTRODUCTION

1.1 BACKGROUND

The recently revised Department of Defense (DoD) acquisition system is documented[1] in:

- DoD Directive 5000.1 (DoDD 5000.1), *The Defense Acquisition System*, dated May 12, 2003
- DoD Instruction 5000.2 (DoDI 5000.2), *Operation of the Defense Acquisition System*, dated May 12, 2003
- *Interim Defense Acquisition Guidebook (Interim Guidebook)*, dated October 30, 2002. This *Interim Guidebook* contains nonmandatory guidance on best practices, lessons learned, and expectations. It is anticipated that the *Interim Guidebook* will be revised in the near future.

A central theme of the acquisition process is that the technology employed in system development should be "mature" before system development begins.[2] Normally, for technology to be considered mature, it must have been applied in a prototype article (a system, subsystem, or component), tested in a relevant or operational environment, and found to have performed adequately for the intended application. This implies a need for a way to measure maturity and for a process to ensure that only sufficiently mature technology is employed.

DoDI 5000.2 establishes a requirement for Technology Readiness Assessments (TRAs), and the *Interim Guidebook* provides an outline of a process for performing TRAs. The *Interim Guidebook* introduces Technology Readiness Levels (TRLs) as an accepted way to describe technology maturity. The National Aeronautics and Space Administration (NASA) has defined TRLs and has used them in its program reviews, and the NASA definitions are the basis for the DoD definitions. A readiness level of TRL 6 or, preferably, TRL

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1 All three of the documents listed are available at http://dod5000.dau.mil/.

2 This reflects a major conclusion of a study performed by the General Accounting Office (GAO). See Appendix A.

7 is normally achieved before a technology is used in system development.[3] Section III of this document addresses TRLs in some detail.

To carry out TRAs, the guidebook describes actions that would normally be taken by Program Managers (PMs), Component Science and Technology (S&T) Executives, Component Acquisition Executives (CAEs), and the Deputy Under Secretary of Defense for Science and Technology (DUSD(S&T)). TRAs must be carried out before Milestone B and Milestone C of acquisition programs categorized as Acquisition Category One (ACAT I): ACAT ID[4] or ACAT IAM.[5]

1.2 PURPOSE OF THIS DOCUMENT

This document is intended to provide DUSD(S&T) staff participants a working appreciation of the overall TRA process, with enough detail to allow them to meet their staff responsibilities. The potential benefit to other Office of the Secretary of Defense (OSD) and Service Component participants is recognized. This "deskbook" should give those involved with TRAs a greater understanding of how TRAs fit into defense acquisition and what is expected by the DUSD(S&T). The DUSD(S&T) serves as the staff proponent for TRAs for the Director for Defense Research and Engineering (DDR&E).

1.3 ORGANIZATION OF THIS DOCUMENT

The body of this document is a concise description of suggested "best practices," responsibilities, roles, and procedures for meeting the TRA requirements of the Defense Acquisition System (DAS).

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3 System development normally begins with a Milestone B decision.

4 ACAT ID is a subcategory of ACAT I. ACAT I programs are Major Defense Acquisition Programs (MDAPs) or programs that the Milestone Decision Authority (MDA) designates ACAT I. An MDAP is an acquisition program that is not a highly sensitive classified program (as determined by the Secretary of Defense) and is designated by the Under Secretary of Defense for Acquisition, Technology, and Logistics USD(AT&L) as an MDAP based on several factors including research, development, test, and evaluation (RDT&E) expenditures and procurement expenditures. The MDA for ACAT ID programs is the USD(AT&L).

5 ACAT IAM is a subcategory of ACAT IA. ACAT IA programs are Major Automated Information Systems (MAISs) or programs designated by the Assistant Secretary of Defense for Networks and Information Integration (ASD(NII)) (formerly the Assistant Secretary of Defense for Command, Control, Communications, and Intelligence (ASD(C3I)) to be ACAT IA. The MDA for ACAT IAM programs is the ASD(NII), who is also the DoD Chief Information Officer (DoD CIO).

The appendixes provide extracts from relevant Government Accounting Office (GAO) and DoD reports (see Appendix A and Appendix B); a policy statement relevant to the TRA process (see Appendix C); examples of TRLs (see Appendix D); specialized definitions and descriptions of TRLs for software (see Appendix E) and for biomedical technology (see Appendix F); comments on Manufacturing Readiness Levels (MRLs) (see Appendix G); and the elements of a Technology Transition Agreement (see Appendix H). The MRLs are not a part of TRAs and are not yet implemented, but they are presented because of their similarity of purpose to TRLs.

1.4 ACQUISITION PROCESS OVERVIEW

Figure I-1 shows the architecture, or framework, of the defense acquisition process. A program to acquire a new system or capability is normally established in response to a recognized user need, but it can also be established to exploit a technological opportunity that might result in a new military capability, a reduced cost, or other benefit. Within this framework, each program can be structured to achieve the best balance of cost, schedule, and performance.

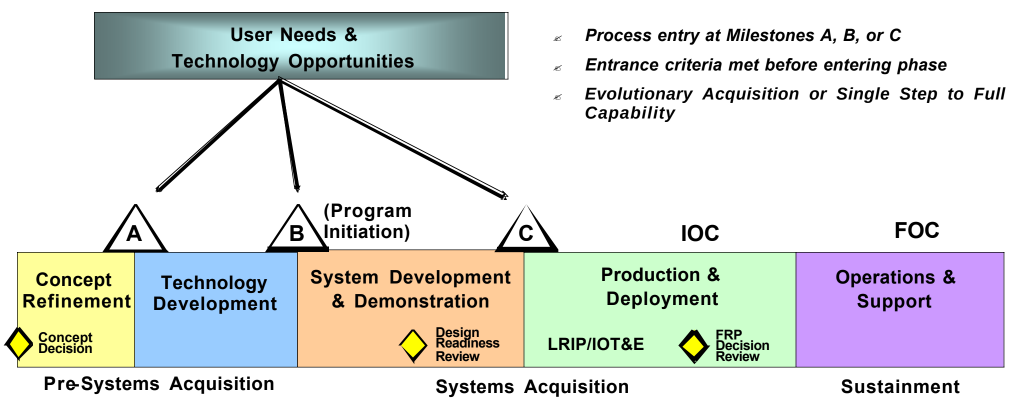

Figure I-1. Defense Acquisition Management Framework (Source: DoDI 5000.2)

The following description of the acquisition system is limited to the elements that impact technology selection, development, and use in defense system acquisition. DoDI 5000.2 contains a far more complete description of the acquisition system.

Consistent with a joint integrated architecture,[6] the Under Secretary of Defense for Acquisition, Technology, and Logistics (USD(AT&L)) leads "the development of integrated plans . . ."[7] With advice from the Chairman of the Joint Chiefs of Staff (CJCS) and the Joint Requirements Oversight Council (JROC), multiple DoD communities "assist in formulating broad, time phased, operational goals, and [in] describing requisite capabilities in [an] Initial Capabilities Document (ICD)."[8] After analysis of potential system concepts, the ICD describes a selected concept based on "robust analyses that consider affordability, technology maturity, and responsiveness."[9]

The ICD and a plan for an Analysis of Alternatives (AoA) are presented to the Milestone Decision Authority (MDA) for approval. Approval initiates Concept Refinement. During Concept Refinement, the selected concept is refined, and alternative technologies (not alternative concepts) are analyzed. This analysis includes consideration of the maturity of the alternative technologies. Whenever the system concept requires technologies that are promising but still unproven, the Component includes a project for maturing the technology in a Technology Development Strategy (TDS). Among other things, the TDS describes how the program will be divided into technology spirals and development increments. The program enters Technology Development (TD) at Milestone A when the MDA approves the TDS. The program is still not considered an acquisition program.[10]

During TD, the technologies required to design and build the system are pursued so that they will be sufficiently mature by Milestone B. TD is a continuous technology discovery and development process that reflects a close collaboration between the user and the system developer and between the system developer and the technology developers.[11] This phase reduces technology risk and determines which technologies are mature and should be integrated into a system. For an evolutionary program, this selection of mature technologies

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6 The joint integrated architectures are developed collaboratively by the USD(AT&L), the ASD(NII) (formerly ASD(C3I), the Joint Staff, the Military Departments, the Defense Agencies, Combatant Commanders, and other appropriate DoD Components. See DoDI 5000.2, paragraph 3.2.1.1.

7 DoDI 5000.2, paragraph 3.2.2.

8 DoDI 5000.2, paragraph 3.4.1.

9 DoDI 5000.2, paragraph 3.4.1.

10 Shipbuilding acquisition programs can be initiated at Milestone A. See DoDI 5000.2, paragraph 3.6.3.

11 The system developer and the technology developers may formalize their association with Technology Transition Agreements. Appendix J contains an example template for an agreement.

applies to the next increment that will have a Milestone B. TD continues for subsequent increments, each of which has its own Milestone B.

A TRA must be conducted before each Milestone B (and before each Milestone C). One of the criteria for exiting TD is that the technology has been demonstrated in a relevant environment.[12] TD demonstrations are used to substantiate technology maturity. These demonstrations should use prototypes or engineering development models (EDMs) at the subsystem level. That is, these items, after detailed design, should be suitable for integration into the system.

During the TD phase, the Joint Staff produces a Capability Development Document (CDD) that builds on the ICD and supports the initiation of an acquisition program. The CDD provides the detailed operational performance parameters necessary to design the proposed system.

The technologies chosen for the system must provide an affordable increment of capability.[13] This requires that the chosen technologies are producible at an acceptable cost and production rate. While not explicit in DoDI 5000.2, this implies that manufacturability and producibility have been considered in the selection of technologies.

Milestone B authorizes a program or increment of a program to enter System Development and Demonstration (SDD). SDD consists of two major efforts (System Integration and System Demonstration) and a mid-phase Design Readiness Review (DRR). System Integration is the system design phase during which the chosen technologies and subsystems are integrated into a detailed system design, and the manufacturing processes are developed. This effort typically includes demonstration of prototype articles or EDMs that result from integration of some or all of the subsystems. The DRR marks the transition to System Demonstration. During System Demonstration prototypes are demonstrated in the intended environment, showing that the system can meet approved requirements.[14] This

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12 DoDI 5000.2, paragraph 3.6.7.

13 DoDI 5000.2, paragraph 3.6.7.

14 After DRR, a Capability Production Document (CPD) is finalized by the Joint Staff, and it is validated and approved before Milestone C. Key Performance Parameters (KPPs) from the CPD are inserted verbatim into the acquisition strategy and the Acquisition Program Baseline (APB). See Chairman of the Joint Chiefs of Staff Manual (CJCSM) 3170.01, *Operation of the Joint Capabilities Integration and Development System,* dated 24 June 2003, Enclosure F paragraphs 1. and 2 (http://www.teao.saic.com/jfcom/ier/documents/m317001.pdf).

phase must also establish that no significant manufacturing risk exists and that industrial capabilities are reasonably available.

A new or revised TRA is required before Milestone C. This TRA should reflect the resolution of any technology deficiencies that arose during SDD and should establish that all critical manufacturing technologies are mature.

Milestone C follows SDD and authorizes Low Rate Initial Production (LRIP). LRIP completes manufacturing development to ensure efficient manufacturing capability and produces production-representative articles for Initial Operational Test and Evaluation (IOT&E).[15]

Approval for Full Rate Production (FRP) depends on demonstrating that critical manufacturing processes are under control and that statistical process control data are being collected.

The framework just described can be tailored to a specific acquisition program structure. For example, the program does not have to start at Concept Refinement. It can start at any point consistent with phase-specific entrance criteria and statutory requirements. If it starts at or beyond Milestone B, an associated TRA is conducted to ensure that the technology is ready for the upcoming phase of acquisition. Normally, a program is not considered an *acquisition program* until it has passed Milestone B.

DoDI 5000.2 establishes evolutionary development as the strategy DoD prefers:

> 3.3.2. The approaches to achieve evolutionary acquisition require collaboration between the user, tester, and developer. They include:
>
> 3.3.2.1. <u>Spiral Development</u>. In this process, a desired capability is identified, but the end-state requirements are not known at program initiation. Those requirements are refined through demonstration and risk management; there is continuous user feedback; and each increment provides the user the best possible capability. The requirements for future increments depend on feedback from users and technology maturation.
>
> 3.3.2.2. <u>Incremental Development</u>. In this process, a desired capability is identified, an end-state requirement is known, and that requirement is met over time by developing several increments, each dependent on available mature technology.

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15 From DoDI 5000.2, 3.8.3.4. "LRIP is not applicable to AISs or software-intensive systems with no developmental hardware; however a limited deployment phase may be applicable. Software shall have demonstrated the maturity level required in the CPD before deploying it to the operational environment." An AIS is an automated information system.

For hardware systems, evolutionary development normally uses incremental development. Each successive design unit is called an increment (Increment 1, Increment 2, and so forth). To ensure that the technology is mature, a TRA is required for each increment before the program has a Milestone B or Milestone C review for that increment.[16]

Software is normally developed using the spiral development process. This is an iterative, cyclical process of build-test-fix-test-deploy. Each release builds on the lessons of the previous release. There can be several releases during the acquisition and deployment of a system or system increment. In the TRA process, software is considered an integral part of the system or subsystem in which it operates. Therefore, demonstration of a technology at the subsystem or system level must include demonstration of the associated software. The Army, for its use, has defined TRLs for software (see Appendix G).

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[16] DoDI 5000.2, paragraph 3.7.2.4 and Table E3.T2.

II. KEY ACTIVITIES AND RELATIONSHIPS

Much of the material in the following paragraphs is based on the *Interim Guidebook*; however, the responsibilities and processes in the guidebook (which is based on DoD 5000.2-R, now canceled) [17] are not mandatory. Therefore, the following is a "suggestion" of activities and relationships that can accomplish the required TRAs.

Before an acquisition program can enter SDD (at Milestone B) or LRIP (at Milestone C), technology maturity must be assessed.[18] DoDI 5000.2, paragraph 3.7.2, establishes as acquisition policy that "… Unless some other factor is overriding in its impact, the maturity of the technology shall determine the path to be followed." Paragraph 3.7.2.2 states that "… If [the] technology is not mature, the DoD Component shall use alternative technology that is mature and that can meet the user's needs."

The PM is an especially important figure in defense acquisition. He/she is responsible for planning and managing each program. The PM normally[19] reports to a Program Executive Officer (PEO), who oversees several PMs. The PEO reports directly to the CAE, who reports through the Component Secretary to the USD(AT&L). Similarly important is the Component S&T Executive. He/she reports to the CAE and is responsible for developing the noncommercial technologies that the Component will need to meet future operational requirements. The DUSD(S&T) has an oversight responsibility for this TD program as part of managing the overall S&T program within DoD.

The *Interim Guidebook* suggests that the Component S&T Executive should be responsible for directing the Component TRAs. For ACAT I and ACAT IA programs, these TRAs are submitted to the CAE for approval, and an information copy is sent to the DUSD(S&T). Subsequently, the CAE transmits the action copy of the TRA to the DUSD(S&T), who is responsible for evaluating each TRA received from a Component.

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[17] A new document to replace the *Interim Guidebook* is being developed.

[18] This is a regulatory requirement. See DoDI 5000.2, Table E3.T2.

[19] For a few special programs, the PM reports directly to the CAE.

The TRA process involves the participation of the PM, the Component S&T Executive, and the DUSD(S&T).[20] Figure II-1 is a nominal timeline for the TRA activities while Figure II-2 displays the principal activities of the DUSD(S&T) Action Officer (AO).

The following paragraphs describe the key activities and people involved in the TRA process. Section IV of this document explores the TRA process in more detail.

2.1 PROGRAM MANAGER (PM)

2.1.1 Requesting Milestone Review Meetings

Most likely, a PM will be designated during TD to guide that development and to prepare for Milestone B. The PM is responsible for requesting Milestone B and C review meetings. For ACAT ID programs, the Defense Acquisition Board (DAB)[21] conducts the review. For ACAT IAM programs, the Information Technology Acquisition Board (ITAB)[22] conducts the review.

Concurrently with scheduling a milestone review meeting, the PM establishes a schedule for the submission of critical technologies. When establishing the schedule for submitting critical technologies, coordination with the Component S&T Executive [and with the DUSD(S&T) for ACAT ID and ACAT IAM programs] is important so that each organization has ample time to complete its respective TRA activities.

2.1.2 Determining Critical Technologies and Disseminating Information

The PM has a fundamental responsibility to know which technologies are critical. A technology is “critical” if the system being acquired depends on this technology to meet capability thresholds, with acceptable development cost and schedule and with acceptable production and operation costs, *and* if the technology or its application is either new or novel. Said another way, a new or novel technology is critical if it is necessary to achieve the successful development of a system, its acquisition, or its operational utility.

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20 Appendix B includes from DoDD 5000.1, DoDI 5000.2, and the *Interim Guidebook* extracts that establish or suggest TRA responsibilities.

21 The DAB is chaired by the USD(AT&L), who is the MDA for ACAT ID programs. The Vice Chairman of the Joint Chiefs of Staff (VCJCS) serves as the vice chairman.

22 The ITAB is chaired by the ASD(NII) (formerly ASD(C3I), who is the DoD CIO and MDA for ACAT IAM programs.

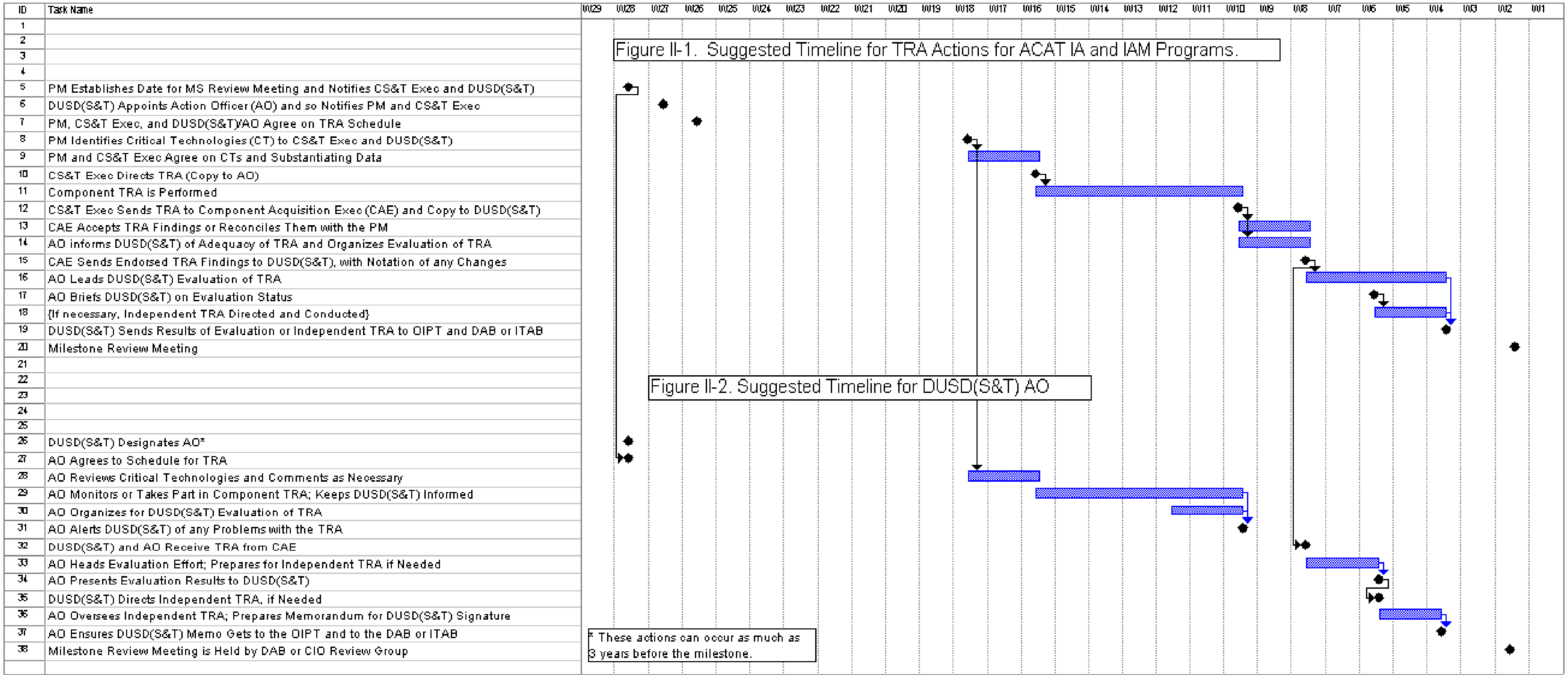

Figure II-1. Suggested Timeline for TRA Actions for ACAT ID and IAM Programs
and
Figure II-2. Suggested Timeline for DUSD(S&T) AO

About 16 weeks before a milestone review (see Figure II-1), on the schedule agreed to with the DUSD(S&T) and the Component S&T Executive, the PM should identify the critical technologies and compile the status, test results, and other information necessary to assess the maturity of these technologies. This identification of critical technologies is an important step in the TRA process. For a readiness assessment to be useful, it must include all the critical technologies. Before identifying the critical technologies, it would be helpful if the PM would send the DUSD(S&T) and the Component S&T Executive a memorandum that describes the identification process that will be used.

After determining the critical technologies, the PM provides this information to the Component S&T Executive and sends an information copy to the DUSD(S&T). Preferably, the identification of critical technologies will have been vetted and agreed upon between the PM and Component S&T Executive. In addition to the list of critical technologies, the PM should explain the function of each technology in the system and provide information on its status. This could include records of tests or applications of the technology. The PM should also provide any additional information requested by the Component S&T Executive or the DUSD(S&T).

If an ACAT ID or ACAT IAM program integrates critical systems or subsystems that are being developed in other programs, the PM of the higher order program, in preparation for a TRA, should identify the critical technologies—including interface technologies—used on his/her side of the interfaces. This PM should request (through the appropriate PEO or CAE, as necessary) and obtain the identification of any critical technologies in the lower order programs. The critical technologies of both the higher order system and all lower order systems or subsystems are included in the list of critical technologies the PM of the higher order system submits to his/her Component S&T Executive and the DUSD(S&T).

If a program has competing designs at the time of the Milestone B or Milestone C review, the critical technologies of each design should be identified separately.

2.2 COMPONENT SCIENCE AND TECHNOLOGY (S&T) EXECUTIVE

2.2.1 Providing the Required Technology

The Component S&T Executive is responsible for developing the noncommercial technologies that will be needed to meet future operational requirements. In addition to advising PMs regarding the status and applicability of technologies, the Component S&T

Executive should work with the PMs to establish how technologies will be matured to support system development programs. During TD, before Milestone B, the Component S&T Executive and Component laboratories will likely be providing some of the resources and effort that the PM has identified in the TD strategy.

2.2.2 Directing the TRA

The *Interim Guidebook* suggests that the Component S&T Executive should direct the TRA and decide how it will be conducted. The TRA must include all critical technologies identified by the PM and can include additional technologies that the Component S&T Executive considers critical. Typically, much of the information used in a TRA comes from the PM; however, the *assessment* must be independent of the PM.

The TRL definitions (see Section III, Table III-1) provide a convenient nomenclature for a technology's maturity status. The Component should use TRLs to relate TRA findings unless alternative means have been coordinated beforehand with the DUSD(S&T).

2.2.3 Processing the TRA Results

For ACAT ID and ACAT IAM programs, the Component S&T Executive signs the TRA (or accompanying memorandum) and accepts responsibility for its accuracy. He/she then submits the TRA to the CAE and, at the same time, sends an information copy to the DUSD(S&T).

2.3 COMPONENT ACQUISITION EXECUTIVE (CAE)

For ACAT ID and ACAT IAM programs, the CAE submits a report to the DUSD(S&T), with an assessed TRL (or some equivalent measure) for each critical technology. This report can consist of a cover letter or memorandum endorsing the Component TRA and officially transmitting that TRA. This should be accomplished according to the agreed-upon schedule—normally, at least 6 weeks before a scheduled Milestone B or Milestone C. See Figure II-1.

2.4 DEPUTY UNDER SECRETARY OF DEFENSE FOR SCIENCE AND TECHNOLOGY (DUSD(S&T))

2.4.1 Preparation and Oversight

The DUSD(S&T) has both oversight and evaluation responsibilities for the TRA. An AO assists, as directed by the DUSD(S&T) (see Figure II-2). While the Component is preparing the TRA, the AO reviews the critical technologies and the identification process, negotiates any perceived deficiencies, and provides oversight. In addition, the AO participates in the TRA to the extent mutually agreed upon with the Component S&T Executive.

2.4.2 Evaluating the Component TRA

The DUSD(S&T) evaluates the Component TRA in cooperation with the Component S&T Executive and the PM. There is no rigid requirement that every critical technology be at a pre-specified TRL by Milestone B or Milestone C. However, for Milestone B, readiness levels of at least TRL 6 are typical (TRL 7 preferred), and, for Milestone C, readiness levels of at least TRL 8 are typical (TRL 9 preferred). At Milestone B, the DUSD(S&T) might conclude that a readiness level of TRL 5 is adequate for a critical technology if a planned and funded program is in place to mature the technology quickly or if a mature backup technology that meets the program requirements and schedule exists. If the Component expects such a conclusion, the supporting information should be provided along with the TRA. At Milestone C, a similar situation could arise—most likely with respect to the manufacturing process technology required to achieve required production rates or cost goals. Section III of this document addresses TRLs in some detail.

After evaluating the Component TRA, the DUSD(S&T) either concurs with the findings or conducts an independent TRA. The DUSD(S&T) forwards either a concurrence with the findings of the Component TRA or the findings of the independent TRA to the Overarching Integrated Product Team (OIPT) and the DAB or to the IT OIPT and the ITAB. This takes place at least 15 days before a Milestone B or Milestone C review meeting (see Figure II-1). If this 15-day window is not possible, the date of the review meeting should be reconsidered so the OIPT and DAB members or the IT OIPT and ITAB members have ample time to review all the relevant information.

2.4.3 Preparing the National Defense Authorization Act (NDAA) Reports for the Secretary of Defense

Sec. 804 of the NDAA for Fiscal Year 2002 Conference Report requires the Secretary of Defense to submit reports on the implementation of the DoD technology readiness policy. The DUSD(S&T) is responsible for preparing these reports. Paragraph 2.7 describes the responsibilities and procedures in more detail.

2.5 CHAIRMAN, OVERARCHING INTEGRATED PRODUCT TEAM (OIPT)

The OIPT [or, in the case of an ACAT IAM program, the Information Technology Overarching Integrated Product Team (IT OIPT)] is led by the appropriate OSD office. It is composed of

- The PM
- The PEO
- Representatives of the Component staff, the USD(AT&L) staff, the ASD(NII)[23] staff, and the Joint Staff
- Other OSD principals involved in the oversight and review of a particular ACAT ID or ACAT IAM program.

The OIPT or IT OIPT provides strategic guidance for the early resolution of issues and conducts oversight and review as a program proceeds through its acquisition life cycle.

2.6 MILESTONE DECISION AUTHORITY (MDA)

The MDA is the individual designated in accordance with criteria established by the USD(AT&L)—or the ASD(NII) for Automated Information System (AIS) acquisition programs—to approve the entry of an acquisition program into the next phase. The DAB or ITAB provides a recommendation to assist the MDA in the decision.

2.7 SECRETARY OF DEFENSE

For each of the calendar years 2002 through 2005, the Secretary of Defense is required to report to Congress on the implementation of DoD policy regarding technology

[23] ASD(NII): This position was formerly the Assistant Secretary of Defense for Command, Control, Communications, and Intelligence (ASD(C3I)).

maturity at the initiation of MDAPs.[24] According to Sec. 804 of the NDAA for Fiscal Year 2002 Conference Report, the reports must

> identify each case in which a major defense acquisition program entered system development and demonstration [i.e., passed Milestone B] during the preceding calendar year and into which key technology has been incorporated that does not meet the technological maturity requirement [i.e., that technology must have been demonstrated in a relevant environment or, preferably, in an operational environment, to be considered mature enough to use for product development in systems integration] … and provide a justification for why such technology was incorporated; and
>
> identify any determination of technological maturity with which the Deputy Under Secretary of Defense for Science and Technology did not concur and explain how the issue has been or will be resolved.

The report for each calendar year must be submitted to the Committees on Armed Services of the Senate and the House of Representatives by March 1 of the following year (i.e., March 1 of years 2003 through 2006).

At the conclusion of each MDAP milestone review, an office designated by the DUSD(S&T) will compile the necessary information for these reports. At the beginning of each calendar year (2003 through 2006), the designated office will prepare the report for the Congressional committees. The DUSD(S&T) will submit the report through the DDR&E to the USD(AT&L) for concurrence and forwarding to the immediate office of the Secretary of Defense. The Secretary of Defense will sign the report or cover letter and submit it to the Congressional committees as required.

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24 This requirement is contained in Sec. 804 of the NDAA for Fiscal Year 2002 Conference Report. Appendix C of this deskbook contains the complete text. The policy to which the Conference Report refers is in the then current DoDI 5000.2, paragraph 4.7.3.2.2.2. In the current version of DoDI 5000.2 (dated May 12, 2003), the corresponding policy statement is in paragraph 3.7.2.2. This latter paragraph states "Technology developed in S&T or procured from industry or other sources shall have been demonstrated in a relevant environment or, preferably, in an operational environment to be considered mature enough to use for product development in systems integration. Technology readiness assessments, and where necessary, independent assessments, shall be conducted. If [the] technology is not mature, the DoD Component shall use alternative technology that is mature and that can meet the user's needs."

III. TRL DEFINITIONS

The *Interim Guidebook* establishes technology maturity levels (i.e., TRLs) as the preferred descriptor of technology maturity for the TRAs required for ACAT ID and ACAT IAM programs. Other means to accomplish a TRA are allowed but should be coordinated in advance by the DUSD(S&T).

Using TRLs to describe the maturity of technologies considered for a new system originated with NASA in the early 1980s. The levels ran from the earliest stages of scientific investigation (Level 1) to successful use in a system (Level 9), which equates to space flight for NASA. DoD has adopted the NASA definitions—with only minor modifications—for the nine TRLs.

Having a strong grasp of the TRL concept is important. The tables in this section give the TRL fundamentals. Table III-1 defines and describes the DoD TRL levels. It also lists typical documentation that should be extracted or referenced to support a TRL assignment. Table III-2 includes a set of additional definitions that help provide a uniform interpretation of the levels.

Software is likely to be an important element in many TRAs. Since the TRL definitions in Table III-1 reflect a systems approach in which software is treated as a part of a component or system, software TRLs are not spelled out specifically in these definitions. However, because some guidelines would be useful in determining the TRLs of the software parts of components and systems, Appendix G provides a set of software TRL definitions developed by the Army.[25]

The TRL definitions in Table III-1 are not readily applied to medical-related items, specifically drugs, vaccines, and medical devices. Their development and use must adhere to Food and Drug Administration (FDA) statutes and policy and to DoD statutes and policy. The Army, in recognition of this situation, took the initiative to establish biomedical TRLs Appendix H provides the excellent result of their efforts.

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25 According to the *Interim Guidebook*, Appendix 6 of that guidebook “lists the various technology readiness levels and descriptions from a systems approach for both HARDWARE and SOFTWARE. DoD Components may provide additional clarifications for Software.”

Table III-1. TRL Definitions, Descriptions, and Supporting Information (Source: *Interim Guidebook*, dated October 30, 2002)

TRL	Definition	Description	Supporting Information
1	Basic principles observed and reported	Lowest level of technology readiness. Scientific research begins to be translated into applied research and development. Examples might include paper studies of a technology's basic properties.	Published research that identifies the principles that underlie this technology. References to who, where, when.
2	Technology concept and/or application formulated	Invention begins. Once basic principles are observed, practical applications can be invented. Applications are speculative, and there may be no proof or detailed analysis to support the assumptions. Examples are limited to analytic studies.	Publications or other references that outline the application being considered and that provide analysis to support the concept.
3	Analytical and experimental critical function and/or characteristic proof of concept	Active research and development is initiated. This includes analytical studies and laboratory studies to physically validate analytical predictions of separate elements of the technology. Examples include components that are not yet integrated or representative.	Results of laboratory tests performed to measure parameters of interest and comparison to analytical predictions for critical subsystems. References to who, where, and when these tests and comparisons were performed.
4	Component and/or breadboard validation in [a] laboratory environment	Basic technological components are integrated to establish that they will work together. This is relatively "low fidelity" compared to the eventual system. Examples include integration of "ad hoc" hardware in the laboratory.	System concepts that have been considered and results from testing laboratory-scale breadboard(s). References to who did this work and when. Provide an estimate of how breadboard hardware and test results differ from the expected system goals.
5	Component and/or breadboard validation in [a] relevant environment	Fidelity of breadboard technology increases significantly. The basic technological components are integrated with reasonably realistic supporting elements so they can be tested in a simulated environment. Examples include "high-fidelity" laboratory integration of components.	Results from testing a laboratory breadboard system that are integrated with other supporting elements in a simulated operational environment. How does the "relevant environment" differ from the expected operational environment? How do the test results compare with expectations? What problems, if any, were encountered? Was the breadboard system refined to match the expected system goals more nearly?

Table III-1. TRL Definitions, Descriptions, and Supporting Information (Source: *Interim Guidebook*, dated October 30, 2002) (Continued)

TRL	Definition	Description	Supporting Information
6	System/subsystem model or prototype demonstration in a relevant environment	Representative model or prototype system, which is well beyond that of TRL 5, is tested in a relevant environment. Represents a major step up in a technology's demonstrated readiness. Examples include testing a prototype in a high-fidelity laboratory environment or in [a] simulated operational environment.	Results from laboratory testing of a prototype system that is near the desired configuration in terms of performance, weight, and volume. How did the test environment differ from the operational environment? Who performed the tests? How did the test compare with expectations? What problems, if any, were encountered? What are/were the plans, options, or actions to resolve problems before moving to the next level?
7	System prototype demonstration in an operational environment	Prototype near, or at, planned operational system. Represents a major step up from TRL 6, requiring demonstration of an actual system prototype in an operational environment such as an aircraft, vehicle, or space. Examples include testing the prototype in a test bed aircraft.	Results from testing a prototype system in an operational environment. Who performed the tests? How did the test compare with expectations? What problems, if any, were encountered? What are/were the plans, options, or actions to resolve problems before moving to the next level?
8	Actual system completed and qualified through test and demonstration	Technology has been proven to work in its final form and under expected conditions. In almost all cases, this TRL represents the end of true system development. Examples include developmental test and evaluation of the system in its intended weapon system to determine if it meets design specifications.	Results of testing the system in its final configuration under the expected range of environmental conditions in which it will be expected to operate. Assessment of whether it will meet its operational requirements. What problems, if any, were encountered? What are/were the plans, options, or actions to resolve problems before finalizing the design?
9	Actual system proven through successful mission operations	Actual application of the technology in its final form and under mission conditions, such as those encountered in operational test and evaluation. Examples include using the system under operational mission conditions.	Operational test and evaluation reports.

Table III-2. Additional Definitions of TRL Descriptive Terms
(Source: *Interim Guidebook*, dated October 30, 2002)

Term	Definition
Breadboard	Integrated components that provide a representation of a system/subsystem and that can be used to determine concept feasibility and to develop technical data. Typically configured for laboratory use to demonstrate the technical principles of immediate interest. May resemble final system/subsystem in function only.
High Fidelity	Addresses form, fit, and function. High-fidelity laboratory environment would involve testing with equipment that can simulate and validate all system specifications within a laboratory setting.
Low Fidelity	A representative of the component or system that has limited ability to provide anything but first-order information about the end product. Low-fidelity assessments are used to provide trend analysis.
Model	A functional form of a system, generally reduced in scale, near or at operational specification. Models will be sufficiently hardened to allow demonstration of the technical and operational capabilities required of the final system.
Operational Environment	Environment that addresses all the operational requirements and specifications required of the final system to include platform/packaging.
Prototype	A physical or virtual model used to evaluate the technical or manufacturing feasibility or military utility of a particular technology or process, concept, end item, or system.
Relevant Environment	Testing environment that simulates the key aspects of the operational environment.
Simulated Operational Environment	Either (1) a real environment that can simulate all of the operational requirements and specifications required of the final system or (2) a simulated environment that allows for testing of a virtual prototype; used in either case to determine whether a developmental system meets the operational requirements and specifications of the final system.

IV. THE TRA PROCESS

4.1 ACTION SEQUENCE FOR A TRA

DoDI 5000.2 includes a description of activities that occur before Milestone A. A collaborative effort produces an ICD that describes the requisite capabilities and time phased, operational goals.[26] The analyses that lead to the ICD identify a preferred concept to be refined before a Milestone A decision. "The MDA designates the lead DoD Component(s) to refine the initial concept selected, approves the AoA plan, and establishes a date for a Milestone A review."[27]

Figure IV-1 graphically portrays the steps that the DUSD(S&T) normally anticipates in the assessment of technology readiness for an ACAT I or IA milestone review. These steps are derived from information in the *Interim Guidebook*, as modified by DoDI 5000.2. However, the information in the guidebook is not mandatory, so the steps are merely suggested.

During Concept Refinement, an AoA is conducted to refine the selected concept.[28] The AoA identifies needed technologies that are not yet mature. A plan for maturing these technologies is then described in a Technology Development Strategy (TDS) which is approved by the MDA at Milestone A. The following phase, TD, matures the technologies and reduces the risk.

Starting during TD, the steps[29] for a Milestone B TRA are as follows:

A. For the system, the PM or Project Leader conducts a risk assessment and develops an Acquisition Program Baseline (APB) and a Work Breakdown Structure (WBS).

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26 DoDI 5000.2, paragraphs 3.2 and 3.4. For more detail see CJCSM 3170.01, *Operation of the Joint Capabilities Integration and Development System,* dated 24 June 2003, Enclosure D. (http://www.teao.saic.com/jfcom/ier/documents/m317001.pdf). A sponsor (e.g., a Service) prepares the ICD. It is approved in the Joint Staff.

27 DoDI 5000.2 paragraph 3.5.2.

28 DoDI 5000.2, enclosure 6, paragraph E6.5, specifies that responsibility for the AoA will not be assigned to the PM. The AoA is directed by the Director, Program Analysis and Evaluation (PA&E) in OSD.

29 The steps that follow (A–J) are marked accordingly in Figure IV-1.

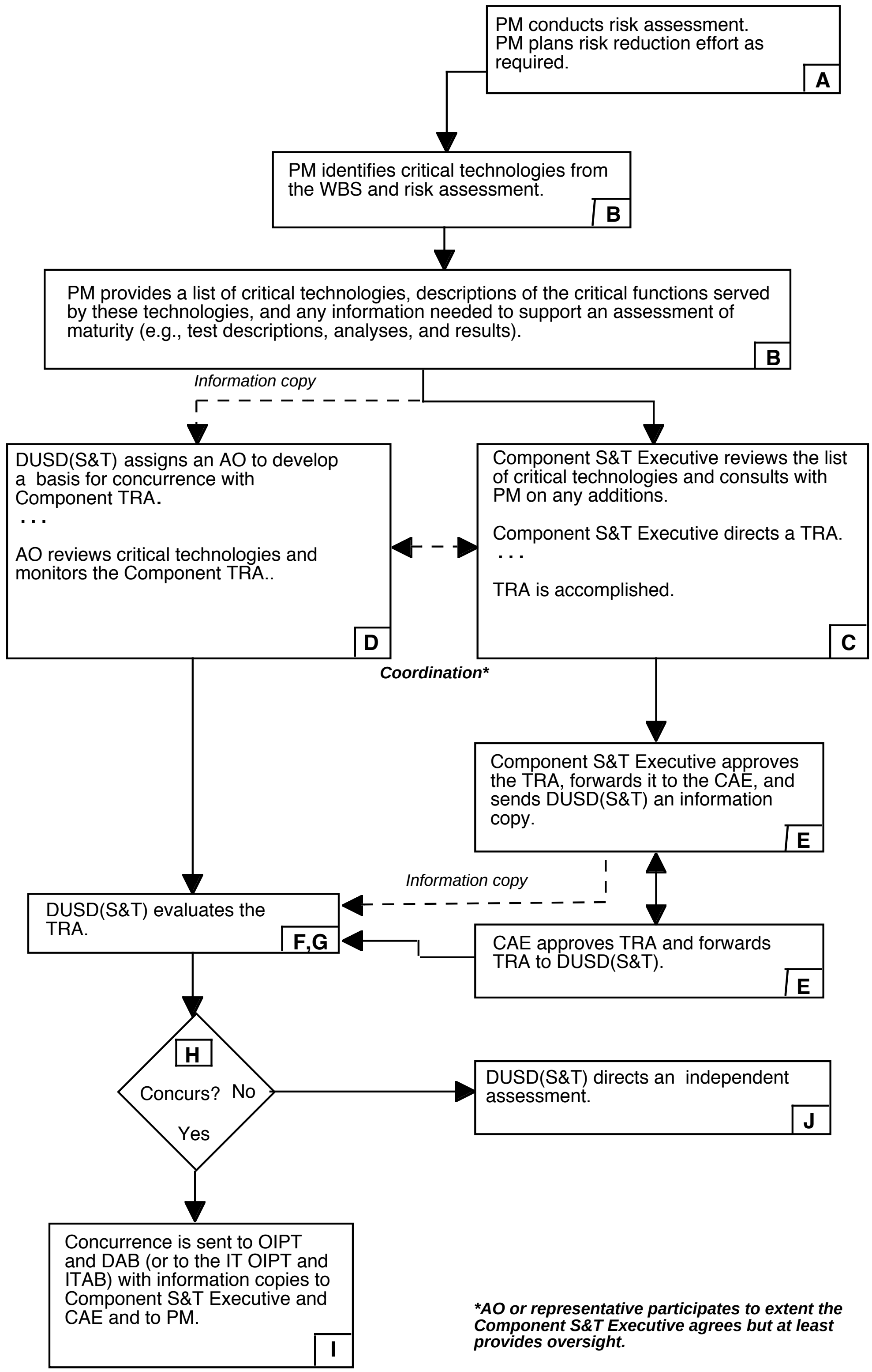

Figure IV-1. Flow Diagram for the TRA Process

B. From the WBS, the risk assessment, and functional analysis, the PM identifies those technologies that are not already fully mature but that are critical to the accomplishment of goals for program cost and schedule and for system producibility, cost, and operational effectiveness. These will be listed as *critical technologies*.

To support the TRA required before an upcoming Milestone B or Milestone C, the PM prepares a list of the critical technologies and a rationale for declaring these technologies to be critical. Substantiating information normally consists of descriptions of the status of components or subsystems, the testing that has been accomplished, and the results of this testing. Test environments and results are described in relation to the functional needs of the system concept. At least 16 weeks before a scheduled Milestone B or Milestone C (see Figure II-1), the list of critical technologies and the supporting information are sent to the Component S&T Executive, with a request for a TRA. At the same time, an information copy is sent to the DUSD(S&T).

C. The Component S&T Executive coordinates with the PM on any additions to the list of critical technologies and on any additional information needed for the TRA.

The Component S&T Executive directs and schedules the accomplishment of a TRA based on the PM's request and submission of the critical technologies information.

The TRA is conducted in accordance with Component guidelines and procedures.

D. The DUSD(S&T) normally appoints a member of his/her staff to act as AO to develop a basis for the DUSD(S&T) to concur with the Component TRA. This basis must be sufficient to fulfill the DUSD(S&T) oversight responsibilities, but it should not be a duplication of the Component TRA.

The AO should review the critical technologies and the identification process, negotiate any perceived deficiencies, and provide oversight while the Component TRA is conducted. The AO should coordinate with the Component S&T Executive to determine to what extent the AO or technology specialists designated by the DUSD(S&T) could or should monitor or participate in the Component TRA. The Component S&T Executive is not required to agree to any such monitoring or participation beyond oversight.

E. When the Component TRA is completed, the Component S&T Executive approves it and forwards it to the CAE. At the same time, the Component S&T Executive sends an information copy to the DUSD(S&T).

Subsequently, the CAE forwards the approved TRA to the DUSD(S&T).

F. The AO develops a basis for DUSD(S&T) concurrence. The approach can be tailored to the specific situation (see paragraph 4.2, which describes one approach). The AO should minimize the impact on the PM and the Component S&T organization but still provide a sound basis for DUSD(S&T) concurrence. Monitoring or participating in the Component TRA will likely facilitate a quick concurrence. If the AO deems any critical technology to be insufficiently mature for the coming milestone, he/she tells the Component S&T Executive and the PM so that all involved have an opportunity to reach agreement on appropriate action.

G. Upon receiving the report and official TRA from the CAE, the AO confirms that it is consistent with the information copy.

H. The AO prepares a memorandum of concurrence or nonconcurrence for signature, presents the staff evaluation of the TRA to the DUSD(S&T), provides whatever backup information is needed, and acts on the DUSD(S&T)'s decision.

I. If the DUSD(S&T) concurs, the concurrence memorandum is transmitted to the OIPT and the DAB or to the IT OIPT and ITAB. This must occur at least 2 weeks before the milestone meeting.

J. If the DUSD(S&T) does not concur, an independent assessment is required. The AO recommends a course of action and prepares a memorandum directing this action. The independent assessment should be a positive contribution to the acquisition program. For example, it could result in a revised, more realistic schedule, in the use of an alternative technology, or in a revised, evolutionary acquisition strategy. The independent assessment should be conducted as quickly as possible—whether this requires 1 day or several months. Typically, the Component funds the independent assessment.

This process (Figure IV-1) applies directly to Milestone B. It can also be applied to Milestone C with minor changes. Before Milestone C, the complete system is demonstrated in its intended environment. This demonstration can use prototypes or EDMs. If the prototypes or EDMs are complete (for the critical technologies), all the critical technologies identified before Milestone B that are used in the system design (i.e., that were not replaced by other, mature technologies) are demonstrated. The TRA conducted in preparation for Milestone C, then, can simply document the use of these technologies and show that the system meets the requirements[30] using these technologies.

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[30] Requirements are documented in the CDD available before Milestone B and in the CPD available before Milestone C.

The TRA for Milestone C should also include any technologies that were found to be critical during SDD. Critical manufacturing processes are identified before the DRR, and these processes could involve critical technologies. If so, these critical technologies should be demonstrated before Milestone C and documented in the TRA. The manufacturing processes themselves, as distinguished from the technology upon which they depend, are not part of the TRA.

The importance of manufacturing and producibility to system development and production, viewed in the light of the fundamentals and benefits of the TRL concept, has led to the idea of Manufacturing Readiness Levels, or MRLs. Within DoD, a Transition Working Group, comprised of representatives from the Military Services, Defense Logistics Agency (DLA), Missile Defense Agency (MDA), and industry, has developed an initial set of definitions and descriptions for MRLs that are suitable for consideration and use in defense acquisition. Appendix I provides these MRL definitions and descriptions. Manufacturing readiness, assessed on the basis of MRLs, is not currently a part of the acquisition system.

Paragraph 4.2 offers an approach to developing the basis for DUSD(S&T) concurrence.

4.2 DUSD(S&T) CONCURRENCE

The DUSD(S&T) is required to evaluate the Component TRA before Milestone B and Milestone C of ACAT ID and ACAT IAM programs. An AO, designated by the DUSD(S&T), will normally lead the evaluation effort.

It is recommended that the AO secure DUSD(S&T) concurrence as follows:

- When the DUSD(S&T) designates an AO, the DUSD(S&T) sends a memorandum to the Directors of his/her staff. This memorandum alerts them to a possible need to provide assistance in their respective technology areas and requests them to designate a point of contact (POC) within their Directorates. If other elements of the USD(AT&L) organization are needed to support the TRA evaluation, that support is also requested by memorandum.
- The AO provides copies of the Component TRA to the designated POCs and invites comments by a certain date.
- The AO reviews the TRA and calls for assistance, as necessary, to obtain a competent assessment of the critical technologies or to determine whether all the critical technologies have been identified.
- If a disagreement with the Component TRA emerges, this is noted in a memorandum to the DUSD(S&T). If the disagreement would jeopardize a favorable

decision by the USD(AT&L) or the ASD(NII), the AO obtains a full explanation (and concurrence with the memorandum) from the cognizant Director.

- The AO conveys the evaluation results to the DUSD(S&T) in a briefing or memorandum. Key Directors attend or coordinate.
- If the DUSD(S&T) does not concur with the Component TRA, the AO prepares the action memorandum to conduct an independent TRA.
- The AO prepares a memorandum for DUSD(S&T) signature. This memorandum gives the evaluation results of the Component TRA and the independent TRA, if conducted. It is sent to the Chairman of the OIPT or IT OIPT and to the Executive Secretary of the DAB or the appropriate staff officer for the ITAB.

V. SUBMITTING A TRA

5.1 SKELETAL TEMPLATE FOR A TRA SUBMISSION

The following outline is a skeletal template for anticipated TRA submissions:

1.0 Purpose of This Document

2.0 Program Overview

2.1 Program Objective

2.2 Program Description

2.3 System Description

3.0 Technology Readiness Assessment

3.1 Process Description

3.2 Critical Technologies

3.3 Assessment of Maturity

3.3.1 First Critical Technology or Category of Technology

3.3.2 Next Critical Technology or Category of Technology

3.4 Summary of TRLs by Technology

4.0 Conclusion

5.2 ANNOTATED TEMPLATE FOR A TRA SUBMISSION

The following outline is an annotated version of the TRA template.[31]

1.0 Purpose of This Document

Should be short and should give the program name, the system name if different from the program name, and the milestone or other decision point for which the TRA was performed. For example, "This document presents an independent Technology Readiness Assessment (TRA) for the UH-60M helicopter program in support of the Milestone B decision. The TRA was performed at the direction of the Army S&T Executive."

2.0 Program Overview

2.1 Program Objective

States what the program is trying to achieve (e.g., new capability, improved capability, lower procurement cost, reduced maintenance or manning, and so forth). Refers to the CDD (for Milestone B) or the Capability Production Document (CPD) (for Milestone C) that documents the program objectives.

2.2 Program Description

Describes the program, not the system. Does the program provide a new system or a modification to an existing operational system? Is it an evolutionary acquisition program? What capabilities will be realized in Block 1? When is the initial operational capability (IOC)? Does it have multiple competing prime contractors? Into what architecture does it fit? Is it a system-of-systems? Does its success depend on the success of other acquisition programs?

2.3 System Description

Describes the overall system, the major subsystems, and components, as necessary, to give an understanding of what is being developed and to show what is new, unique, or special about it. This should include the systems, components, and

[31] Appendix F contains two examples of TRA submissions to OSD.

technologies that will later be declared “critical technologies.” Describes how the system works (if this is not obvious).

3.0 Technology Readiness Assessment

3.1 Process Description

Tells who led the TRA and what organizations or individuals performed the TRA. Identifies the special expertise of participating organizations or individuals. This should establish the competence and the independence of the TRA. In this context, “independence” means that the assessors are not unduly influenced by the opinions of the developers (government or industry). Usually, the PM or the System Program Office (SPO) will provide most of the data and other information that form the basis of a TRA. Nevertheless, the *assessment* should be *independent* of the PM or SPO.

States what analyses and investigations were performed when making the assessment (e.g., examination of test setups, discussions with test personnel, analysis of test data, review of related technology, and so forth).

This is only a broad description of the process. Paragraph 3.3 presents an opportunity to include more detail.

3.2 Critical Technologies

Lists the technologies included in the TRA. A table that lists the technology name and includes a few words that describe the technology and its function is appropriate. The technologies can be organized according to the WBS, as provided by the PM. The names of these critical technologies should be used consistently throughout the remainder of the document.

The PM should identify the critical technologies. The Component S&T Executive should assess at least these technologies; however, other technologies that the Component S&T Executive considers critical can also be included.

3.3 Assessment of Maturity

3.3.1 First Critical Technology or Category of Technology

Describes the technology (subsystem, component, or technology). Describes the function it performs and, if needed, how it relates to other parts of the system. Provides a synopsis of TD history and status. This can include facts about related uses of the same or similar technology, numbers or hours of testing of breadboards, numbers of prototypes built and tested, relevance of the test conditions, and results achieved. Finally, applies the criteria for TRLs and assigns a readiness level to the technology. States the readiness level (e.g., TRL 5) and the rationale for choosing this readiness level.

For a complex system, if the critical technologies presented are in categories (e.g., airframe or sensors), the information specified in the previous paragraph (e.g., describing the technology, describing the function it performs, and so forth) should be provided for each critical technology within a category.

3.3.2 Next Critical Technology or Category of Technology

This paragraph and the following paragraphs (e.g., 3.3.3, 3.3.4, and so forth) present for other critical technologies the same type of information that was presented in paragraph 3.3.1.

3.4 Summary of TRLs by Technology

Presents a table that lists the critical technologies and, for each critical technology, presents the TRL assigned and a short explanation (one sentence or a list of factors).

4.0 Conclusion

States the Component S&T Executive's position concerning the maturity of the technologies and whether this maturity is adequate for the system to enter the next stage of development. If the position is supportive of entering the next stage even though some critical technologies are less mature than would ordinarily be expected, explains what circumstances or planned work justifies the positive position.

The TRA should be signed “Approved By” the Component S&T Executive, or it should be transmitted with a cover memorandum that clearly states that the TRA represents the position of the Component S&T Executive. In effect, the Component S&T Executive must certify that he/she stands behind the statements in the Conclusion.

GLOSSARY

ACAT	Acquisition Category
AIS	Automated Information System
AO	Action Officer
AoA	Analysis of Alternatives
APB	Acquisition Program Baseline
ASD(C3I)	Assistant Secretary of Defense for Command, Control, Communications, and Intelligence
ASD(NII)	Assistant Secretary of Defense for Networks and Information Integration
CAE	Component Acquisition Executive
CDD	Capability Development Document
CJCS	Chairman of the Joint Chiefs of Staff
CJCSM	Chairman of the Joint Chiefs of Staff Manual
CPD	Capability Production Document
DAB	Defense Acquisition Board
DAS	Defense Acquisition System
DDR&E	Director of Defense Research and Engineering
DLA	Defense Logistics Agency
DoD CIO	DoD Chief Information Officer
DoD	Department of Defense
DoDD	Department of Defense Directive
DoDI	Department of Defense Instruction
DRR	Design Readiness Review
DUSD(S&T)	Deputy Under Secretary of Defense for Science and Technology
EDM	engineering development model
FOC	full operational capability
FRP	full-rate production
GAO	Government Accounting Office
ICD	Initial Capabilities Document
IOC	initial operational capability
IOT&E	Initial Operational Test and Evaluation

IT OIPT	Information Technology Overarching Integrated Product Team
ITAB	Information Technology Acquisition Board
JROC	Joint Requirements Oversight Council
KPP	key performance parameter
LRIP	low rate initial production
MAIS	Major Automated Information System
MDA	Milestone Decision Authority Missile Defense Agency
MDAP	Major Defense Acquisition Program
MRL	Manufacturing Readiness Level
NASA	National Aeronautics and Space Administration
NDAA	National Defense Authorization Act
ODDR&E	Office of the Director of Defense Research and Engineering
OIPT	Overarching Integrated Product Team
OSD	Office of the Secretary of Defense
PA&E	Program Analysis and Evaluation
PEO	Program Executive Officer
PM	Program Manager
POC	point of contact
RDT&E	research, development, test, and evaluation
S&T	Science and Technology
SDD	System Development and Demonstration, a phase in the DAS
SPO	System Program Office
T&E	test and evaluation
TD	Technology Development
TDS	Technology Development Strategy
TRA	Technology Readiness Assessment
TRL	Technology Readiness Level
USD(AT&L)	Under Secretary of Defense for Acquisition, Technology, and Logistics
VCJCS	Vice Chairman of the Joint Chiefs of Staff
WBS	Work Breakdown Structure

APPENDIXES FOR THE
TECHNOLOGY READINESS ASSESSMENT (TRA) DESKBOOK

APPENDIX A
SUMMARY OF GENERAL ACCOUNTING OFFICE (GAO) REPORTS AND DEPARTMENT OF DEFENSE (DoD) IMPLEMENTATION

Several GAO reports addressed the DoD acquisition system and made recommendations that influenced the DoD 5000 series of publications. The following presents a brief summary of GAO-related work, along with references for the source documents.

A.1 GAO REPORTS

The subcommittee on Readiness and Management Support of the Committee on Armed Services, U.S. Senate, which has oversight on acquisitions policy, enlisted the GAO in a study of best commercial practices as related to defense acquisition. A series of GAO reports and related testimony assessed how best commercial practices could improve the way DoD incorporates new technology into weapon system programs and reduces risk. These reports, issued from 1996–2000 (the principal of which are listed as Refs. 1, 2, 3), offered DoD some guidance and had significant influence on the current versions of the DoD 5000 series of documents [Department of Defense Directive (DoDD) 5000.1, Department of Defense Instruction (DoDI) 5000.2, and the *Interim Defense Acquisition Guidebook* (formerly DoD 5000.2-R)] (Refs. 4, 5, 6).

The weapon system acquisition cycle for DoD major weapon systems before the issuance of References 4, 5, and 6 could be illustrated as shown in Figure A-1. Technology, design, and manufacturing knowledge was obtained concurrently.

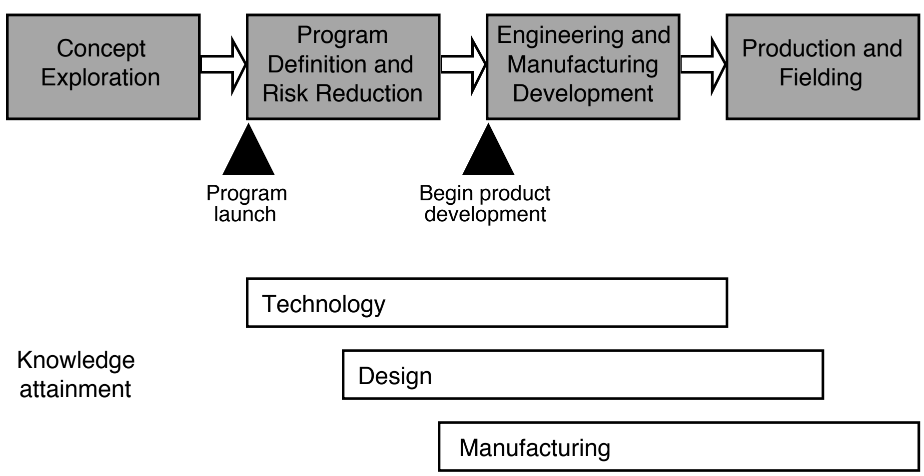

Figure A-1. DoD's Current Weapon System Acquisition Cycle

The major GAO recommendation that followed best commercial practice is to minimize technology development during product development and match requirements with technological capability before product development is launched. Proof that the technology will work and can be demonstrated to a high level of maturity is critical to lowering risk and avoiding large cost overruns. Associated with this principle are the needs to develop high

standards for finding the maturity and readiness of technology, to establish disciplined paths that technology must take to be included in products, and to provide strong gate-keepers to decide when to allow the technology into a product development program. GAO recommended that DoD not launch a program until the technologies needed to meet a new weapons requirement are mature. To separate this technology development from the program, GAO best practices recommendations suggest that a technology and concept maturation phase follow concept exploration and precede program launch, as illustrated in Figure A-2.

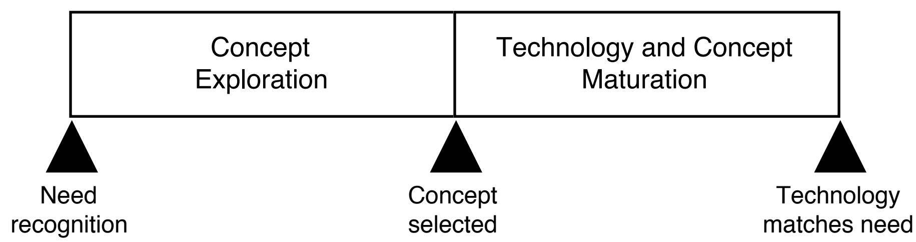

Figure A-2. Weapon Acquisition Phases That Should Precede the Launch of a New Program

The GAO review of best practices for including new technology in products (see Ref. 2) applied a scale of Technology Readiness Levels (TRLs) pioneered by the National Aeronautics and Space Administration (NASA) and adapted by the Air Force Research Laboratory (AFRL). "TRLs proved to be reliable indicators of the relative maturity of the 23 technologies reviewed, both commercial and military, and their eventual success after they were included in product development programs" (Ref. 2, p. 22)

To show that design is mature, the GAO studies suggest that a product development phase should include a distinct system integration effort *before* the system demonstration effort to demonstrate the effectiveness of the product and processes. See Figure A-3.

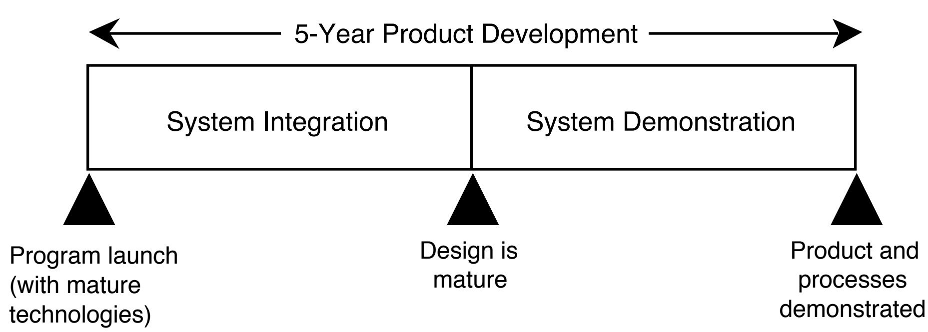

Figure A-3. Product Development Phase To Deliver a Mature Design and Key Processes

Figure A-4 shows GAO's final proposal for a potential DoD technology and product development process based on commercial best practices. It should be noted that leading commercial firms launch a new product later than DoD—after technology is complete. Paragraphs A.2 and A.3 of this appendix provide the GAO recommendations for DoD management of Technology Development and the DoD response as reported in Reference 2. DoD did not agree entirely with GAO's recommendations and is willing to accept more risk. DoD considered TRL 6 as an acceptable readiness-level risk for a weapon system entering the program definition stage (see Figure A-1) and TRL 7 as an acceptable readiness-level risk for the Engineering and Manufacturing Development (EMD) stage. GAO accepted this.

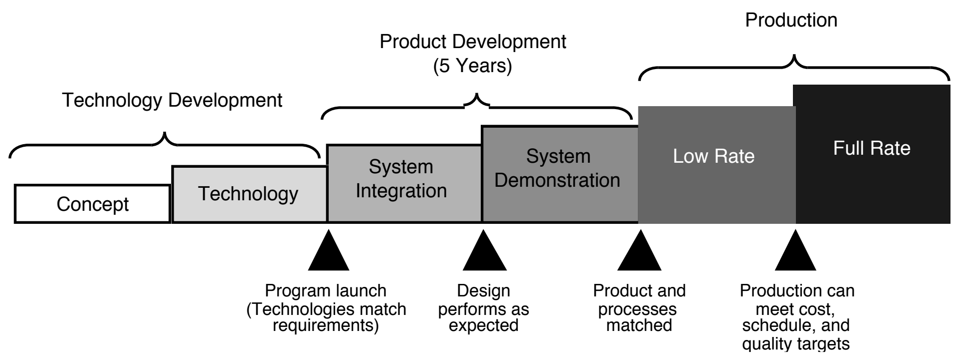

Figure A-4. Potential DoD Technology and Product Development Process Incorporating Best Practices

Figure A-5 outlines the current Defense Acquisition Management Framework presented in DoD 5000.2, dated May 12, 2003. The relationship to the GAO recommendation of Figure A-4 is evident.

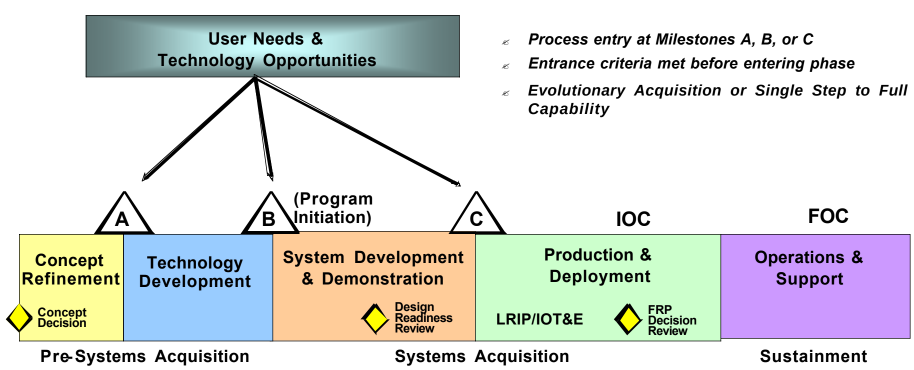

Figure A-5. Defense Acquisition Management Framework

A.2 GAO RECOMMENDATIONS

The following paragraphs are direct quotations from Reference 2: GAO/NSIAD-99-162, *Best Practices: Better Management of Technology Development Can Improve Weapon System Outcomes*.

> We have previously recommended that DOD separate technology development from weapon system programs. That recommendation was made without prejudice toward the necessity of technology development but rather with the intent that programs could be better managed if such development was conducted outside of a program manager's purview. Similarly, the recommendations that follow are made without prejudice toward-or the intention of compromising-the basic research and other activities that S&T organizations perform. We recognize that implementation of these recommendations will have organizational, funding, and process implications and will require the cooperation of the Congress (p. 62).
>
> To help ensure that new technologies are vigorously pursued and successfully moved into weapon system programs, we recommend that the Secretary of Defense adopt a disciplined and knowledge-based method for assessing technology maturity, such as TRLs, DOD-wide. This practice should employ standards for assessing risks of handoff to program managers that are based on a technology's level of demonstration and its criticality to meeting the weapon system's requirements (p.63).
>
> With these tools in hand, we recommend that the Secretary (1) establish the place at which a match is achieved between key technologies and weapon system requirements as the proper time for committing to the cost, schedule, and performance baseline for developing and producing that weapon system and (2) require that key technologies reach a high maturity level—analogous to TRL 7-before making that commitment. This would approximate the launch point for product development as practiced by leading commercial firms (p. 63).
>
> We recommend that the Secretary find ways to ensure that the managers responsible for maturing the technologies and designing weapon systems before product development are provided the more flexible environment that is suitable for the discovery of knowledge, as distinct from the delivery of a product. Providing more flexibility will require the cooperation of requirements managers and resource managers so that rigid requirements or the threat of jeopardizing the funding planned to start product development will not put pressure on program managers to accept immature technologies. Such an environment may not be feasible if the program definition and risk reduction phase remains the effective launch point for an entire weapon system program (p. 63).
>
> An implication of these recommendations is that S&T organizations will have to play a greater role in maturing technologies to higher levels and should be funded accordingly. Therefore, we recommend that the Secretary of Defense evaluate the different ways S&T organizations can play a greater role in helping technologies reach high levels of maturity before product

development begins. For example, given that a technology has sufficient potential for application to a weapon system, at a minimum, an S&T organization should be responsible for taking a technology to TRL 6 before it is handed off to a program office at the program definition and risk reduction phase. During this phase, the program manager would be responsible for maturing the technology to TRL 7 before it is included in an engineering and manufacturing development program. In a situation where a single, design-pacing technology is to be developed for a known application—like the non-penetrating periscope—an S&T organization should be required to mature that technology to TRL 7 before it is turned over to a product development manager. S&T organizations could play a similar role when a significant new technology is being prepared for insertion into an existing weapon system. Finally, when multiple new technologies are to be merged to create a weapon system, S&T organizations should be required to bring key technologies to TRL 6 and then become part of a hybrid organization with product developers to integrate the technologies and bring them to TRL 7 before handing full responsibility to a product development manager (pp. 63–64).

To help guard against the possibility that the more basic research and technology development activities would be compromised by having S&T organizations routinely take key technologies to TRL 6 or higher, we recommend that the Secretary extract lessons from the nonpenetrating periscope, the AAAV, and the Army's Future Scout programs, and other ATD and ACTD programs. Specifically, the Secretary should assess whether the resources needed to enable S&T organizations to play a leading role in the development of technologies and, in some cases, preliminary system design, detracted from or displaced more basic research and technology development programs (p. 64).

Finally, we recommend that the Secretary empower managers of product development programs to refuse to accept key technologies with low levels of demonstrated maturity. The Secretary can encourage this behavior through supportive decisions on individual programs, such as by denying proposals to defer the development of key technologies and by favoring proposals to lengthen schedules or lessen requirements to reduce technological risk early (p. 64).

A.3 DoD COMMENTS AND GAO EVALUATION

The following paragraphs are direct quotations from Reference 2: GAO/NSIAD-99-162, *Best Practices: Better Management of Technology Development Can Improve Weapon System Outcomes*.

DOD generally concurred with a draft of this report and its recommendations, noting that the traditional path to new weapon system development is no longer affordable or necessary (see app. I). DOD stated that it has embarked upon a "Revolution in Business Affairs" that will enable new technologies to be developed more efficiently and effectively. It believes that the first steps in this direction have already been taken but agrees that more progress needs to be made. DOD agreed that TRLs are necessary in assisting decision-makers in deciding on when and where to insert new

technologies into weapon system programs and that weapon system managers should ensure that technology is matured to a TRL 7 before insertion occurs. DOD concurred that S&T organizations should be involved in maturing technologies to high levels, such as TRL 6, before transitioning to the engineering and manufacturing development phase and agreed to assess the impact of this involvement on other S&T resources. We note that the best practice is to mature technology to at least a TRL 7 before starting the engineering and manufacturing development phase, whether the technology is managed by an S&T organization, a weapon system program manager, or a hybrid of the two organizations (pp. 64–65).

DOD noted that while TRLs are important and necessary, the increasing projected life for new weapon systems, total ownership costs, and urgency based upon threat assessments are also important considerations for system development decisions. We agree and note that our recommendations are not intended to cover all aspects of weapon system development decisions or to suggest that technology maturity is the only factor in such decisions. Rather, the recommendations are in keeping with the purpose of the report, "to determine whether best practices offer methods to improve the way DOD matures new technology so that it can be assimilated into weapon system programs with less disruption." We believe that a knowledge-based approach to maturing technology, such as TRLs, can benefit other considerations as well. For example, decisions on what technologies to include in a weapon system and when to include them can have a significant bearing on its total ownership costs.

DOD stated that there should be an established point for the transition of technologies and that it plans to supplement its milestone review process with additional guidance in the next revisions to DOD 5000.2-R. It also stated that its policy on the evolutionary approach to weapon acquisitions should be developed in consonance with the technology transition strategy. We cannot comment on the revisions to the directive or the evolutionary acquisition policy because they have yet to be published. However, under the current milestone review process, the pressures placed on a program during the program definition and risk reduction phase—when much technology development occurs—can operate against the flexibility and judgments that are needed to mature technologies. If the revisions to the directive supplement the current milestones without relieving the pressures brought to bear on programs as they are launched in the program definition and risk reduction phase, it will remain difficult to discourage the acceptance of immature technologies in the design of new weapon systems. To relieve these pressures, we encourage DOD, as it develops the directive and the evolutionary acquisition policy, to separate technology development from product development and to redefine the launch point for a program as the point at which enough knowledge has been gained to ensure that a match is reached between the maturity of key technologies and weapon system requirements (pp. 65–66).

DOD also stated that program managers already have the ability to reject inappropriately mature technologies, and to the extent technology immaturity affects acquisition baselines, to advise acquisition executives of feasible alternatives. We did not find this to be the case in our review. Rather, we

found that the program managers' ability to reject immature technologies is hampered by (1) untradable requirements that force acceptance of technologies despite their immaturity and (2) reliance on tools for judging technology maturity that fail to alert the managers of the high risks that would prompt such a rejection. As noted in the report, once a weapon system program begins, the environment becomes inflexible and deviations to program baselines can attract unwanted attention. This reality limits the program managers' ability to reject immature technologies (p. 66).

A.4 REFERENCES

1. GAO/T-NSIAD 99-116, *Defense Acquisition: Best Commercial Practices Can Improve Program Outcomes*. Statement for the Record by Louis J. Rodrigues, Director, Defense Acquisition Issues, National Security and International Affairs Division. Testimony Before the Subcommittee on Readiness and Management Support, Committee on Armed Services, U.S. Senate, March 1999.
   (See Internet Web site http://www.fas.org/man/gao/nsiad-99-116.htm).
2. GAO/NSIAD-99-162, *Best Practices: Better Management of Technology Development Can Improve Weapon System Outcomes*. United States General Accounting Office (GAO) Report to the Chairman and Ranking Minority Member, Subcommittee on Readiness and Management Support, Committee on Armed Services, U.S. Senate, July 1999.
   (See Internet Web site http://www.fas.org/man/gao/nsiad-99-162.htm).
3. GAO/T-NSIAD-00-137, *Defense Acquisition: Employing Best Practices Can Shape Better Weapon System Decisions*. Statement of David M. Walker, Comptroller General of the United States. Testimony Before the Subcommittee on Readiness and Management Support, Committee on Armed Services, U.S. Senate, April 26, 2000.
   See Internet Web site http://www.gao.gov/archive/2000/ns00137t.pdf).
4. DoDD 5000.1, *The Defense Acquisition System, May 12, 2003*
   (See Internet Web site http://dod5000.dau.mil/index.htm).
5. DoDI 5000.2, *Operation of the Defense Acquisition System*, *May 12, 2003*
   (See Internet Web site http://dod5000.dau.mil/index.htm).
6. *Interim Defense Acquisition Guidebook, October 30, 2002,* [formerly DoD 5000.2-R, *Mandatory Procedures for Major Defense Acquisition Programs (MDAP) and Major Automated Information System (MAIS) Acquisition Programs,* April 5, 2002].
   (See Internet Web site http://dod5000.dau.mil/index.htm).

ACRONYMS AND ABBREVIATIONS FOR APPENDIX A

AAAV	Advanced Amphibious Assault Vehicle
ACAT	Acquisition Category
ACTD	Advanced Concept Technology Demonstration
AFRL	Air Force Research Laboratory
ASD(C3I)	Assistant Secretary of Defense for Command, Control, Communications, and Intelligence
ATD	Advanced Technology Demonstration
CAE	Component Acquisition Executive
DAB	Defense Acquisition Board
DoD	Department of Defense
DoDD	Department of Defense Directive
DoDI	Department of Defense Instruction
DUSD(S&T)	Deputy Under Secretary of Defense for Science and Technology
EMD	Engineering and Manufacturing Development
FOC	full operational capability
GAO	General Accounting Office
IOC	initial operational capability
LRIP	low rate initial production
MAIS	Major Automated Information System
MDAP	Major Defense Acquisition Program
MNS	Mission Needs Statement
NASA	National Aeronautics and Space Administration
NSIAD	National Security and International Affairs Division (GAO)
ODDR&E	Office of the Director of Defense Research and Engineering
ODUSD(S&T)	Office of the Deputy Under Secretary of Defense for Science and Technology
ORD	Operational Requirements Document
PM	Program Manager
S&T	Science and Technology
TRA	Technology Readiness Assessment
TRL	Technology Readiness Level
USD(AT&L)	Under Secretary of Defense for Acquisition, Technology, and Logistics

APPENDIX B
EXTRACTS FROM THE DEPARTMENT OF DEFENSE (DoD) 5000 SERIES OF DOCUMENTS RELEVANT TO TECHNOLOGY READINESS ASSESSMENTS (TRAs) AND A COMMENT ON THE TRA PROCESS

The DoD 5000 series documents relevant to TRAs are

- Department of Defense Directive (DoDD) 5000.1, *The Defense Acquisition System,* dated May 12, 2003.
- Department of Defense Instruction (DoDI) 5000.2, *Operation of the Defense Acquisition System,* dated May 12, 2003.
- *Interim Defense Acquisition Guidebook,* dated October 30, 2002, [formerly DoD 5000.2-R, *Mandatory Procedures for Major Defense Acquisition Programs (MDAPs) and Major Automated Information System (MAIS) Acquisition Programs*, dated April 5, 2002)].

For background and reference, portions of these documents relevant to Technology Readiness. These DoD 5000 series documents appear on Internet Web site http://dod5000.dau.mil/.

B.1 EXTRACTS FROM DoD 5000 SERIES DOCUMENTS RELEVANT TO TECHNOLOGY READINESS ASSESSMENT

B.1.1 DoDD 5000.1, dated May 12, 2003

- **Policy**

  4.3. The following policies shall govern the Defense Acquisition System:

  4.3.1. Flexibility. There is no one best way to structure an acquisition program to accomplish the objective of the Defense Acquisition System. MDAs and PMs shall tailor program strategies and oversight, including documentation of program information, acquisition phases, the timing and scope of decision reviews, and decision levels, to fit the particular conditions of that program, consistent with applicable laws and regulations and the time-sensitivity of the capability need.

  4.3.2. Responsiveness. Advanced technology shall be integrated into producible systems and deployed in the shortest time practicable. Approved, time-phased capability needs matched with available technology and resources enable evolutionary acquisition strategies. Evolutionary acquisition strategies are the preferred approach to satisfying operational needs. Spiral development is the preferred process for executing such strategies.

- **Enclosure 1: Additional Policy**

  E1.14. Knowledge-Based Acquisition. PMs shall provide knowledge about key aspects of a system at key points in the acquisition process. PMs shall reduce technology risk, demonstrate technologies in a relevant environment, and identify technology alternatives, prior to program initiation. They shall reduce

integration risk and demonstrate product design prior to the design readiness review. They shall reduce manufacturing risk and demonstrate producibility prior to full-rate production.

E1.28. Technology Development and Transition. The Science and Technology (S&T) program shall:

E.1.28.1. Address user needs;

E.1.28.2. Maintain a broad-based program spanning all Defense-relevant sciences and technologies to anticipate future needs and those not being pursued by civil or commercial communities;

E1.28.3. Preserve long-range research; and

E.1.28.4. Enable rapid, successful transition from the S&T base to useful military products.

B.1.2 DoDI 5000.2, dated May 12, 2003

- **Applicability and Scope**

  2.2. All defense technology projects and acquisition programs. Some requirements, where stated, apply only to Major Defense Acquisition Programs (MDAPs) and Major Automated Information System (MAIS) programs.

- **User Needs and Technology Opportunities**

  3.4.1. The capability needs and acquisition management systems shall use Joint Concepts, integrated architectures, and an analysis of doctrine, organization, training, materiel, leadership, personnel, and facilities (DOTMLPF) in an integrated, collaborative process to define desired capabilities to guide the development of affordable systems. The Chairman of the Joint Chiefs of Staff, with the assistance of the Joint Requirements Oversight Council, shall assess and provide advice regarding military capability needs for defense acquisition programs. The process through which the Chairman provides his advice is described in Chairman of the Joint Chiefs of Staff Instruction 3170.01 (reference (g)). Representatives from multiple DoD communities shall assist in formulating broad, time-phased, operational goals, and describing requisite capabilities in the Initial Capabilities Document (ICD). They shall examine multiple concepts and materiel approaches to optimize the way the Department of Defense provides these capabilities. The examination shall include robust analyses that consider affordability, technology maturity, and responsiveness.

Concept Refinement

3.5.2. Concept Refinement begins with the Concept Decision. The MDA designates the lead DoD Component(s) to refine the initial concept selected,

approves the AoA plan, and establishes a date for a Milestone A review. The MDA decisions shall be documented in an Acquisition Decision Memorandum (ADM). This effort shall normally be funded only for the concept refinement work. The MDA decision to begin Concept Refinement DOES NOT mean that a new acquisition program has been initiated. The tables in enclosure 3 identify all statutory and regulatory requirements for the Concept Refinement decision.

3.5.3. The ICD and the AoA plan shall guide Concept Refinement. The focus of the AoA is to refine the selected concept documented in the approved ICD. The AoA shall assess the critical technologies associated with these concepts, including technology maturity, technical risk, and, if necessary, technology maturation and demonstration needs. To achieve the best possible system solution, emphasis shall be placed on innovation and competition. Existing commercial-off-the-shelf (COTS) functionality and solutions drawn from a diversified range of large and small businesses shall be considered.

- **Technology Development**

3.6.1. Purpose. The purpose of this phase is to reduce technology risk and to determine the appropriate set of technologies to be integrated into a full system. Technology Development is a continuous technology discovery and development process reflecting close collaboration between the S&T community, the user, and the system developer. It is an iterative process designed to assess the viability of technologies while simultaneously refining user requirements.

3.6.2. The project shall enter Technology Development at Milestone A when the MDA has approved the TDS. The tables in enclosure 3 identify all statutory and regulatory requirements applicable to Milestone A. This effort normally shall be funded only for the advanced development work. For business area capabilities, commercially available solutions shall be employed. (A toolkit of best practices is available at http://deskbook.dau.mil). A favorable Milestone A decision DOES NOT mean that a new acquisition program has been initiated.

3.6.3. Shipbuilding programs may be initiated at the beginning of Technology Development. The information required in the tables at enclosure 3 shall support program initiation. A cost assessment shall be prepared in lieu of an independent cost estimate (ICE), and a preliminary assessment of the maturity of key technologies shall be provided.

- **System Development and Demonstration**

3.7.1. Purpose

3.7.1.2. SDD has two major efforts: System Integration and System Demonstration. The entrance point is Milestone B, which is also the initiation of an acquisition program. There shall be only one Milestone B per program or evolutionary increment. Each increment of an evolutionary acquisition shall have

its own Milestone B. The tables in enclosure 3 identify the statutory and regulatory requirements that shall be met at Milestone B. For Shipbuilding Programs, the required program information shall be updated in support of the Milestone B decision, and the ICE shall be completed. The lead ship in a class shall normally be authorized at Milestone B. Technology readiness assessments shall consider the risk associated with critical subsystems prior to ship installation. Long lead for follow ships may be initially authorized at Milestone B, with final authorization and follow ship approval by the MDA dependent on completion of critical subsystem demonstration and an updated assessment of technology maturity.

3.7.2. Entrance Criteria. Entrance into this phase depends on technology maturity (including software), approved requirements, and funding. Unless some other factor is overriding in its impact, the maturity of the technology shall determine the path to be followed. Programs that enter the acquisition process at Milestone B shall have an ICD that provides the context in which the capability was determined and approved, and a CDD that describes specific program requirements.

3.7.2.2. The management and mitigation of technology risk, which allows less costly and less time-consuming systems development, is a crucial part of overall program management and is especially relevant to meeting cost and schedule goals. Objective assessment of technology maturity and risk shall be a routine aspect of DoD acquisition. Technology developed in S&T or procured from industry or other sources shall have been demonstrated in a relevant environment or, preferably, in an operational environment to be considered mature enough to use for product development in systems integration. Technology readiness assessments, and where necessary, independent assessments, shall be conducted. If technology is not mature, the DoD Component shall use alternative technology that is mature and that can meet the user's needs.

- **Enclosure 3: Statutory, Regulatory, and Contract Reporting Information and Milestone Requirements**

  E.3.1. Tables E3.T1, E3.T2, and E3.T3[1], below, show the information requirements for all milestones and phases, both statutory and regulatory, to include contract reporting. MDAs may tailor regulatory program information to fit the particular conditions of an individual program. A non-mandatory guidebook

[1] The parts of Tables E3.T1 and E3.T2 relevant to this discussion are included. Table E3.T3 is not included in this appendix (Appendix B to the TRA Deskbook).

Table E3.T1. Statutory Information Requirements

Information Required	Applicable Statute	When Required
The following information requirements are statutory for both MDAPs and MAIS acquisition programs		
Consideration of Technology Issues	10 U.S.C. 2364, reference (q)	Milestone (MS) A MS B MS C
The following information requirements are statutory for MDAPs and are applicable to MAIS acquisition programs by this Instruction		
Technology Development Strategy (TDS)	Sec. 803, Pub.L. 107-314, reference (an)	MS A MS B MS C

Table E3.T2. Regulatory Information Requirements

Information Required	Source	When Required
Technology Readiness Assessment	This Instruction	Program Initiation for Ships (preliminary assessment) MS B MS C
Independent Technology Assessment (ACAT ID only) (if required by DUSD(S&T))	This Instruction	MS B MS C
Command, Control, Communications, Computers, and Intelligence Support Plan (C4ISP) (also summarized in the acquisition strategy)	DoD Instruction 4630.8 and DoD Directive 4630.5, references (ar) and (as)	Program Initiation for Ships MS B MS C

shall support this Instruction to provide best practices, lessons learned, and expectations for the information required by these tables. Issues regarding the intent of the expectations described in the guidebook shall be resolved by the MDA. The AT&L Knowledge Sharing System (formerly Defense Acquisition Deskbook) contains a library of mandatory policy and regulations and discretionary practices and advice. The Internet Web site address is http://deskbook.dau.mil/.

E.3.2. The following Statutory Information Requirements Table is divided into sections to indicate which information requirements are applicable to MDAPs, MAIS programs, or both. MAIS programs that are also MDAPs are subject to both sets of statutory requirements.

B.1.3 *INTERIM DEFENSE ACQUISITION GUIDEBOOK*, DATED OCTOBER 30, 2002

The extracts below are taken directly from the *Interim Guidebook* and reflect their origin in the former DoD 5000.2-R. While using these extracts, the reader should keep the FOREWORD to the Guidebook in mind.

> The Deputy Secretary's memorandum, *Defense Acquisition,* dated October 30, 2002, and Attachment 2 to that memorandum reference a guidebook to accompany the interim guidance. The former DoD 5000.2-R regulation will serve as the guidebook while the Defense Acquisition Policy Working Group creates a streamlined guidebook. The former DoD 5000.2-R is NOT mandatory, but should be used for best practices, lessons learned, and expectations, until replaced.

Subsequent to publication of the streamlined guidebook, the Technology Readiness Assessment (TRA) Deskbook will be updated to reflect its content.

- **Technology Maturity**

  C7.5.1. Technology maturity shall measure the degree to which proposed critical technologies meet program objectives. Technology maturity is a principal element of program risk. A technology readiness assessment shall examine program concepts, technology requirements, and demonstrated technology capabilities to determine technological maturity.

  C7.5.2. The PM shall identify critical technologies via the WBS. (See paragraph C5.3.1.)[2] Technology readiness assessments for critical technologies shall occur sufficiently prior to milestone decision points B and C to provide useful technology maturity information to the acquisition review process.

  C7.5.3. The DoD Component Science and Technology (S&T) Executive shall direct the technology readiness assessment and, for ACAT ID and ACAT IAM programs, submit the findings to the CAE who shall submit his or her report to the DUSD(S&T) with a recommended technology readiness level (TRL) (or some equivalent assessment) for each critical technology. When the Component S&T Executive submits his or her findings to the CAE, he or she shall provide the DUSD(S&T) an information copy of those findings. In cooperation with the Component S&T Executive and the program office, the DUSD(S&T) shall evaluate the technology readiness assessment and, if he/she concurs, forward findings to the OIPT leader and DAB. If the DUSD(S&T) does not concur with the technology readiness assessment findings, an independent technology readiness assessment, under the direction of the DUSD(S&T), shall be required.

  C7.5.4. TRL descriptions appear at Appendix 6.[3] TRLs enable consistent, uniform, discussions of technical maturity, across different types of technologies. Decision authorities shall consider the recommended TRLs (or some equivalent assessment methodology, e.g., Willoughby templates) when assessing program risk. TRLs are a measure of technical maturity. They do not discuss the

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2 For paragraph C5.3.1, see Section B.4 of this appendix.

3 These definitions also appear in Section III of this TRA Deskbook.

probability of occurrence (i.e., the likelihood of attaining required maturity) or the impact of not achieving technology maturity.

- **Integrated Product Teams (IPTs) in the Oversight and Review Process**

  C7.6.4.4. For ACAT ID decision points, the OIPT leader shall provide the DAB chair, principals, and advisors an integrated assessment using information gathered through the IPT process. The leader's assessment shall focus on core acquisition management issues and shall consider independent assessments, including technology readiness assessments, which the OIPT members normally prepare. These assessments typically occur in context of the OIPT review, and shall be reflected in the OIPT leader's report. There shall be no surprises at this point--all team members shall work issues in real time and shall be knowledgeable of their OIPT leader's assessment. OIPT and other staff members shall not require the PM to provide pre-briefs independent of the OIPT process.

  C7.6.7. Independent Assessments. Assessments, independent of the developer and the user, ensure an impartial evaluation of program status. Consistent with statutory requirements and good management practice, the Department of Defense shall require independent assessments of program status (e.g., the independent cost estimate or technology readiness assessment). Senior acquisition officials shall consider these assessments when making acquisition decisions. Staff offices that provide independent assessments shall support the orderly and timely progression of programs through the acquisition process. IPTs shall have access to independent assessments to enable full and open discussion of issues.

B.2 EXTRACTS FROM THE *INTERIM DEFENSE ACQUISITION GUIDEBOOK* THAT SUGGEST TRA RESPONSIBILITIES

B.2.1 Program Manager (PM)

C7.3.1.4. The PM shall brief the acquisition program to the DAB and specifically emphasize technology maturity, risk management, affordability, critical program information, technology protection, and rapid delivery to the user. The PM shall address any interoperability and supportability requirements linked to other systems, and indicate whether those requirements will be satisfied by the acquisition strategy under review. If the program is part of a system-of-systems architecture, the PM shall brief the DAB in that context. If the architecture includes less than ACAT I programs that are key to achieving the expected operational capability, the PM shall also discuss the status of and dependence on those programs.

C7.3.2.3. Principal participants at DoD CIO reviews shall include (as appropriate to the issue being examined) the following department officials: the Deputy DoD CIO; IT OIPT Leader; ACAT ID OIPT Leaders; Cognizant PEO(s) and PM(s); Cognizant OSD PSA; CAEs and CIOs of the Army, the Navy, and the Air Force. Participants shall also include (as appropriate to the issue being examined) executive-level representatives from the following organizations: Office of USD(AT&L); Office of the Under Secretary of Defense (Comptroller); Office of the Joint Chiefs of Staff; Office of DOT&E; Office of the Director, PA&E; and Defense Information Systems Agency.

C7.5.2. The PM shall identify critical technologies via the WBS. (See paragraph C5.3.1.)[4] Technology readiness assessments for critical technologies shall occur sufficiently prior to milestone decision points B and C to provide useful technology maturity information to the acquisition review process.

C7.6.4.1. All ACAT ID and IAM programs shall have an OIPT to provide assistance, oversight, and review as the program proceeds through its acquisition life cycle. An appropriate official within OSD, typically the Director of Strategic and Tactical Systems or the Principal Director, Command, Control, Communications, Intelligence, Surveillance, and Reconnaissance & Space, shall lead the OIPT for ACAT ID programs. The Deputy DoD CIO or designee shall lead the OIPT for ACAT IAM programs. The OIPT for ACAT IAM programs is called the IT OIPT. OIPTs shall comprise the PM, PEO, DoD Component Staff, Joint Staff, and OSD staff involved in oversight and review of the particular ACAT ID or IAM program.

C7.6.5.1. The PM, or designee, shall form and lead an IIPT to support the development of strategies for acquisition and contracts, cost estimates, evaluation of alternatives, logistics management, training, cost-performance trade-offs, etc. The PM, assisted by the IIPT, shall develop and propose to the OIPT, a WIPT structure. The IIPT shall coordinate the activities of the WIPTs and review issues they do not address. WIPTs shall meet as required to help the PM plan program structure and documentation and resolve issues. While there is no one-size-fits-all WIPT approach, the following basic tenets shall apply:

C7.6.5.1.1. The PM is in charge of the program.

C7.6.5.1.2. IPTs are advisory bodies to the PM.

C76.5.1.3. Direct communication between the program office and all levels in the acquisition oversight and review process is expected as a means of exchanging information and building trust.

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4 For paragraph C5.3.1, see Section B.4 of this appendix.

C7.7.1. It shall be DoD policy to keep reporting requirements to a minimum. Nevertheless, complete and current program information is essential to the acquisition process. Consistent with the tables of required regulatory and statutory information appearing in reference (a), decision authorities shall require PMs and other participants in the defense acquisition process to present only the minimum information necessary to understand program status and make informed decisions. The MDA shall "tailor-in" program information case-by-case, as necessary. IPTs shall facilitate the management and exchange of program information.

C7.14.1. PMs shall implement internal management controls in accordance with DoD Directive 5000.1 (reference (di)), DoD Instruction 5000.2 (reference (a)), this Regulation, and DoD Directive 5010.38 (reference (dj)). APB parameters shall serve as control objectives. PMs shall identify deviations from approved APB parameters and exit criteria as materiel weaknesses. PMs shall focus on results, not process.

C7.15.1.1. Program plans describe the detailed activities of the acquisition program. In coordination with the PEO, the PM shall determine the type and number of program plans needed to manage program execution.

B.2.2 Deputy Under Secretary of Defense for Science and Technology DUSD(S&T)

C7.5.3. The DoD Component Science and Technology (S&T) Executive shall direct the technology readiness assessment and, for ACAT ID and ACAT IAM programs, submit the findings to the CAE who shall submit his or her report to the DUSD(S&T) with a recommended technology readiness level (TRL) (or some equivalent assessment) for each critical technology. When the Component S&T Executive submits his or her findings to the CAE, he or she shall provide the DUSD(S&T) an information copy of those findings. In cooperation with the Component S&T Executive and the program office, the DUSD(S&T) shall evaluate the technology readiness assessment and, if he/she concurs, forward findings to the OIPT leader and DAB. If the DUSD(S&T) does not concur with the technology readiness assessment findings, an independent technology readiness assessment, under the direction of the DUSD(S&T), shall be required.

C7.6.7. Independent Assessments. Assessments, independent of the developer and the user, ensure an impartial evaluation of program status. Consistent with statutory requirements and good management practice, the Department of Defense shall require independent assessments of program status (e.g., the independent cost estimate or technology readiness assessment). Senior acquisition officials shall consider these assessments when making acquisition

decisions. Staff offices that provide independent assessments shall support the orderly and timely progression of programs through the acquisition process. IPTs shall have access to independent assessments to enable full and open discussion of issues.

B.2.3 Component Acquisition Executive (CAE)

C7.5.3. The DoD Component Science and Technology (S&T) Executive shall direct the technology readiness assessment and, for ACAT ID and ACAT IAM programs, submit the findings to the CAE who shall submit his or her report to the DUSD(S&T) with a recommended technology readiness level (TRL) (or some equivalent assessment) for each critical technology. When the Component S&T Executive submits his or her findings to the CAE, he or she shall provide the DUSD(S&T) an information copy of those findings. In cooperation with the Component S&T Executive and the program office, the DUSD(S&T) shall evaluate the technology readiness assessment and, if he/she concurs, forward findings to the OIPT leader and DAB. If the DUSD(S&T) does not concur with the technology readiness assessment findings, an independent technology readiness assessment, under the direction of the DUSD(S&T), shall be required.

B.2.4 Component Science and Technology (S&T) Executive

C7.5.3. The DoD Component Science and Technology (S&T) Executive shall direct the technology readiness assessment and, for ACAT ID and ACAT IAM programs, submit the findings to the CAE who shall submit his or her report to the DUSD(S&T) with a recommended technology readiness level (TRL) (or some equivalent assessment) for each critical technology. When the Component S&T Executive submits his or her findings to the CAE, he or she shall provide the DUSD(S&T) an information copy of those findings. In cooperation with the Component S&T Executive and the program office, the DUSD(S&T) shall evaluate the technology readiness assessment and, if he/she concurs, forward findings to the OIPT leader and DAB. If the DUSD(S&T) does not concur with the technology readiness assessment findings, an independent technology readiness assessment, under the direction of the DUSD(S&T), shall be required.

B.2.5 Defense Acquisition Board [Chaired by the Under Secretary of Defense for Acquisition Technology and Logistics (USD(AT&L))]

C7.3.1.1. The DAB shall advise the USD(AT&L) on critical acquisition decisions. The USD(AT&L) shall chair the DAB, and the Vice Chairman of the Joint Chiefs of Staff shall serve as vice-chair. DAB membership shall comprise

the following executives: Under Secretary of Defense (Comptroller); Under Secretary of Defense (Policy); Under Secretary of Defense (Personnel & Readiness); ASD(C3I)/DoD CIO; DOT&E; and the Secretaries of the Army, the Navy, and the Air Force. United States Joint Forces Command shall be available to comment on interoperability and integration issues that the JROC forwards to the DAB. The DAE may ask other department officials to participate in reviews, as required.

B.2.6 Defense Acquisition Executive (DAE)

C7.3.1.3. The DAE shall conduct DAB reviews at major program milestones and at the Full-Rate Production Decision Review (if not delegated to the CAE), and at other times, as necessary. An ADM shall document the decision(s) resulting from the review.

B.2.7 DoD Chief Information Officer (CIO) Reviews

C7.3.2.1. DoD CIO Reviews shall provide the forum for ACAT IAM milestones, for deciding critical ACAT IAM issues when they cannot be resolved at the OIPT level, and for enabling the execution of the DoD CIO's acquisition-related responsibilities for IT, including NSS, under the Clinger-Cohen Act and Title 10 U.S.C. (references (bn) and (dd)). Wherever possible, these reviews shall take place in the context of the existing IPT and acquisition milestone review process. Where appropriate, an ADM shall typically document the decision(s) resulting from the review.

B.2.8 Overarching Integrated Product Team (OIPT)

C7.6.4.1. All ACAT ID and IAM programs shall have an OIPT to provide assistance, oversight, and review as the program proceeds through its acquisition life cycle. An appropriate official within OSD, typically the Director of Strategic and Tactical Systems or the Principal Director, Command, Control, Communications, Intelligence, Surveillance, and Reconnaissance & Space, shall lead the OIPT for ACAT ID programs. The Deputy DoD CIO or designee shall lead the OIPT for ACAT IAM programs. The OIPT for ACAT IAM programs is called the IT OIPT. OIPTs shall comprise the PM, PEO, DoD Component Staff, Joint Staff, and OSD staff involved in oversight and review of the particular ACAT ID or IAM program.

C7.6.4.2. The OIPT shall form upon departmental intention to start an acquisition program. The OIPT shall charter the IIPT and WIPTs. The OIPT shall consider the recommendations of the IIPT regarding the appropriate milestone for program initiation and the minimum information needed for the program initiation milestone review. OIPTs shall meet, thereafter, as necessary over the

life of the program. The OIPT leader shall act to resolve issues when requested by any member of the OIPT, or when so directed by the MDA. The goal is to resolve as many issues and concerns at the lowest level possible, and to expeditiously escalate issues that need resolution at a higher level. The OIPT shall bring only the highest-level issues to the MDA for decision.

C7.6.4.3. The OIPT shall normally convene 2 weeks before a planned decision point. It shall assess the information and recommendations that the MDA will receive, in the same context, and to the same ACAT level. It shall also assess family-of-system or system-of-system capabilities within mission areas in support of mission area operational architectures developed by the Joint Staff. If the program includes a pilot project, such as TOC Reduction, the PM shall report the status of the project to the OIPT. The OIPT shall then assess progress against stated goals. The PM's briefing to the OIPT shall specifically address interoperability and supportability (including spectrum supportability) with other systems, anti-tamper provisions, and indicate whether those requirements will be satisfied by the acquisition strategy under review. If the program is part of a family-of-systems architecture, the PM shall brief the OIPT in that context. If the architecture includes less than ACAT I programs that are key to achieving the expected operational capability, the PM shall also discuss the status of and dependence on those programs. The OIPT leader shall recommend to the MDA whether the anticipated review should go forward as planned.

C7.6.4.4. For ACAT ID decision points, the OIPT leader shall provide the DAB chair, principals, and advisors an integrated assessment using information gathered through the IPT process. The leader's assessment shall focus on core acquisition management issues and shall consider independent assessments, including technology readiness assessments, which the OIPT members normally prepare. These assessments typically occur in context of the OIPT review, and shall be reflected in the OIPT leader's report. There shall be no surprises at this point--all team members shall work issues in real time and shall be knowledgeable of their OIPT leader's assessment. OIPT and other staff members shall not require the PM to provide pre-briefs independent of the OIPT process.

B.2.9 Integrated Product Teams (IPTs)

C7.6.2. IPTs are an integral part of the defense acquisition oversight and review process. For ACAT ID and IAM programs, there are generally two levels of IPT: the OIPT and WIPT(s). Each program shall have an OIPT and at least one WIPT. WIPTs shall focus on a particular topic such as cost/performance, test, or contracting. An Integrating IPT (IIPT) (which is a WIPT) shall coordinate WIPT efforts and cover all topics not otherwise assigned to another IPT.

IPT participation is the primary way for any organization to participate in the acquisition program.

B.2.10 Authority of Key Acquisition System Officials: From DoDD 5000.1

5.1. The USD(AT&L), the Assistant Secretary of Defense (Command, Control, Communications, and Intelligence), and the Director of Operational Test and Evaluation are key officials of the Defense Acquisition System. Consistent with their respective authorities, they may jointly issue DoD Instructions, DoD Publications, and one-time directive-type memoranda, consistent with DoD 5025.1-M (reference (c)), that implement the policies contained in this Directive. Financial Management Enterprise Architecture (FMEA) Requirements shall be addressed for all financial management and mixed (financial and non-financial) information systems and shall be certified as being compliant with the FMEA by the Under Secretary of Defense (Comptroller) (USD(C)).

B.3 A COMMENT ON THE TRA PROCESS

The *Interim Defense Acquisition Guidebook* (October 30, 2002)

Appendix 6 of the *Interim Defense Acquisition Guidebook* lists 9 TRLs and their definitions.[5] The specific level for passing MS B and MS C is not directed. Nonetheless, the wording "… in an appropriate simulated environment, or preferably in an operational environment" strongly suggests TRL 6 or TRL 7 at MS B.

B.4 REFERENCES

- **From DoDI 5000.2, *Operation of the Defense Acquisition System,* dated May 12, 2003 (see Paragraph B.1.2 of this appendix)**
  - (g) Chairman of the Joint Chiefs of Staff Instruction 3170.01 Series, "Requirements Generation System," April 15, 2001.
  - (q) Section 2364 of title 10, United States Code, "Coordination and Communication of Defense Research Activities."
  - (an) Section 803, Public Law 107-314, "Bob Stump National Defense Authorization Act for Fiscal Year 2003," "Spiral development under major defense acquisition programs."

5 These definitions also appear in Section III of this TRA Deskbook.

- (ar) DoD Instruction 4630.8, “Procedures for Interoperability and Supportability of Information Technology (IT) and National Security Systems (NSS),” May 2, 2002.
- (as) DoD Directive 4630.5, “Interoperability and Supportability of Information Technology (IT) and National Security Systems (NSS),” January 11, 2002.

- **From the *Interim Defense Acquisition Guidebook,* dated October 30, 2002 (see Paragraph B.2.1 of this appendix)**
  - (a) DoD Instruction 5000.2, “Operation of the Defense Acquisition System,” April 5, 2002.
  - (di) DoD Directive 5000.1, “The Defense Acquisition System,” October 23, 2000.
  - (dj) DoD Directive 5010.38, “Management Control (MC) Program,” August 26, 1996.
- **From the *Interim Defense Acquisition Guidebook,* dated October 30, 2002 (see paragraphs B.1.3 and B.2.1 of this appendix)**
  - **Paragraph C5.3.1.** Work Breakdown Structure (WBS). Systems engineering shall yield a program WBS. The PM shall prepare the WBS in accordance with the WBS guidance in MIL-HDBK-881 (reference (cj)). The WBS provides the framework for program and technical planning, cost estimating, resource allocation, performance measurement, technical assessment, and status reporting. The WBS shall include the WBS dictionary. The WBS shall define the system to be developed or produced. It shall display the system as a product-oriented family tree composed of hardware, software, services, data, and facilities. It shall relate the elements of work to each other and to the end product. The PM shall normally specify contract WBS elements only to level three for prime contractors and key subcontractors. Only low-level elements that address high-risk, high-value, or high-technical-interest areas of a program shall require detailed reporting below level three. The PM shall have only one WBS for each program.

ACRONYMS AND ABBREVIATIONS FOR APPENDIX B

ACAT	Acquisition Category
ADM	Acquisition Decision Memorandum
AoA	Analysis of Alternatives
APB	Acquisition Program Baseline
ASD(C3I)	Assistant Secretary of Defense for Command, Control, Communications, and Intelligence
AT&L	Acquisition, Technology, and Logistics
C4ISP	Command, Control, Communications, Computers, and Intelligence Support Plan
CAE	Component Acquisition Executive
CDD	Capability Development Document
CIO	Chief Information Officer
COTS	commercial-off-the-shelf
DAB	Defense Acquisition Board
DAE	Defense Acquisition Executive
DDL	Delegation of Disclosure Authority Letter
DoD	Department of Defense
DoDD	Department of Defense Directive
DoDI	Department of Defense Instruction
DOT&E	Director of Operational Test and Evaluation
DOTMLPF	doctrine, organization, training, materiel, leadership, personnel, and facilities
DUSD(S&T)	Deputy Under Secretary of Defense for Science and Technology
FMEA	Financial Management Enterprise Architecture
ICD	Initial Capabilities Document
ICE	independent cost estimate
IIPT	Integrating IPT
IPT	Integrated Product Team
IT	Information Technology
JROC	Joint Requirements Oversight Committee
MAIS	Major Automated Information System
MDA	Milestone Decision Authority
MDAP	Major Defense Acquisition Program

MS	Milestone
NSS	National Security Systems
OIPT	Overarching Integrated Product Team
OSD	Office of the Secretary of Defense
PA&E	Program Analysis and Evaluation
PEO	Program Executive Officer
PM	Program Manager
PSA	Principal Staff Assistant
S&T	Science and Technology
SDD	System Development and Demonstration
TDS	Technology Development Strategy
TOC	total ownership cost
TRA	Technology Readiness Assessment
TRL	Technology Readiness Level
USC	United States Code
USD(AT&L)	Under Secretary of Defense for Acquisition, Technology, and Logistics
USD(C)	Under Secretary of Defense (Comptroller)
WBS	Work Breakdown Structure
WIPT	Working Integrated Product Team

APPENDIX C
POLICY STATEMENT

A congressional directive is provided here.

107TH CONGRESS *1st Session*	HOUSE OF REPRESENTATIVES	REPORT 107–333

NATIONAL DEFENSE AUTHORIZATION ACT FOR FISCAL YEAR 2002

CONFERENCE REPORT

TO ACCOMPANY

S. 1438

DECEMBER 12, 2001.—Ordered to be printed

SEC. 804. REPORTS ON MATURITY OF TECHNOLOGY AT INITIATION OF MAJOR DEFENSE ACQUISITION PROGRAMS.

(a) REPORTS REQUIRED.—Not later than March 1 of each of years 2003 through 2006, the Secretary of Defense shall submit to the Committees on Armed Services of the Senate and the House of Representatives a report on the implementation of the requirement in paragraph 4.7.3.2.2.2 of Department of Defense Instruction 5000.2, as in effect on the date of enactment of this Act, that technology must have been demonstrated in a relevant environment (or, preferably, in an operational environment) to be considered mature enough to use for product development in systems integration.

(b) CONTENTS OF REPORTS.—Each report required by subsection (a) shall—

(1) identify each case in which a major defense acquisition program entered system development and demonstration during the preceding calendar year and into which key technology has been incorporated that does not meet the technological maturity requirement described in subsection (a), and provide a justification for why such key technology was incorporated; and

(2) identify any determination of technological maturity with which the Deputy Under Secretary of Defense for Science and Technology did not concur and explain how the issue has been or will be resolved.

(c) MAJOR DEFENSE ACQUISITION PROGRAM DEFINED.—In this section, the term "major defense acquisition program" has the meaning given that term in section 139(a)(2) of title 10, United States Code.

APPENDIX D
TECHNOLOGY READINESS LEVEL (TRL) EXAMPLES

Table III-1 of the TRA Deskbook contains the definitions of the various TRLs and notes some of the information that supports assignment of a technology to specific levels of readiness. To aid in making the definitions more concrete, this appendix contains several examples of readiness levels for technologies as the evolved to full maturity.

6 Compliments of the Army, in which the evolution of a technology is depicted graphically.

7 Compliments of the Navy, in which the evolution of a materials technology is presented, with a full description at each TRL.

RING LASER GYRO

Technology Readiness Example

Level	Technology Readiness	Example – HG1700 Inertial Measurement Unit Guided Multiple Launch Rocket System (GMLRS)
1	Basic Principles observed and reported	**Basic research** – Invention of Gas Laser
2	Technology concept and/or application formulated.	**Basic research** – Invention of Ring Laser. Theoretical description of Ring Laser Gyro
3	Analytical and experimental critical function and/or characteristic proof of concept.	**Applied research** – Demonstration of Ring Laser as a rate sensor
4	Component and/or breadboard validation in laboratory environment.	**Applied research** – Demonstration of Ring Laser Gyro (RLG)-based Inertial Measurement Unit (IMU) operation under temperature, shock, vibration, and g-loading
5	Component and/or breadboard validation in relevant environment.	**Advanced Technology Demonstration** – Demonstration of HG1700-based guidance set components (IMU, GPS receiver, control system, flight computer) in a high-fidelity hardware-in-the-loop facility
6	System/subsystem model or prototype demonstrated in a relevant environment.	**Advanced Technology Demonstration** – Demonstration of actual flight-ready HG1700-based guidance set in a high-fidelity hardware-in-the-loop facility and under expected levels of shock, vibration, altitude and temperature
7	System prototype demonstrated in an operational environment.	**System Design and Development** – Demonstration of actual Guided MLRS missile in a flight test sequence from an operational launcher. Successful operation in multiple flight demonstrations
8	Actual system completed and "flight qualified" through test and demonstration.	**Low Rate Initial Production** – Developmental Test and Evaluation of GMLRS in its final form under mission conditions.
9	Actual system "flight proven" through successful mission operations.	**Production** – Operational Test and Evaluation of GMLRS by the soldier, airman, or seaman.

Technology Readiness Example

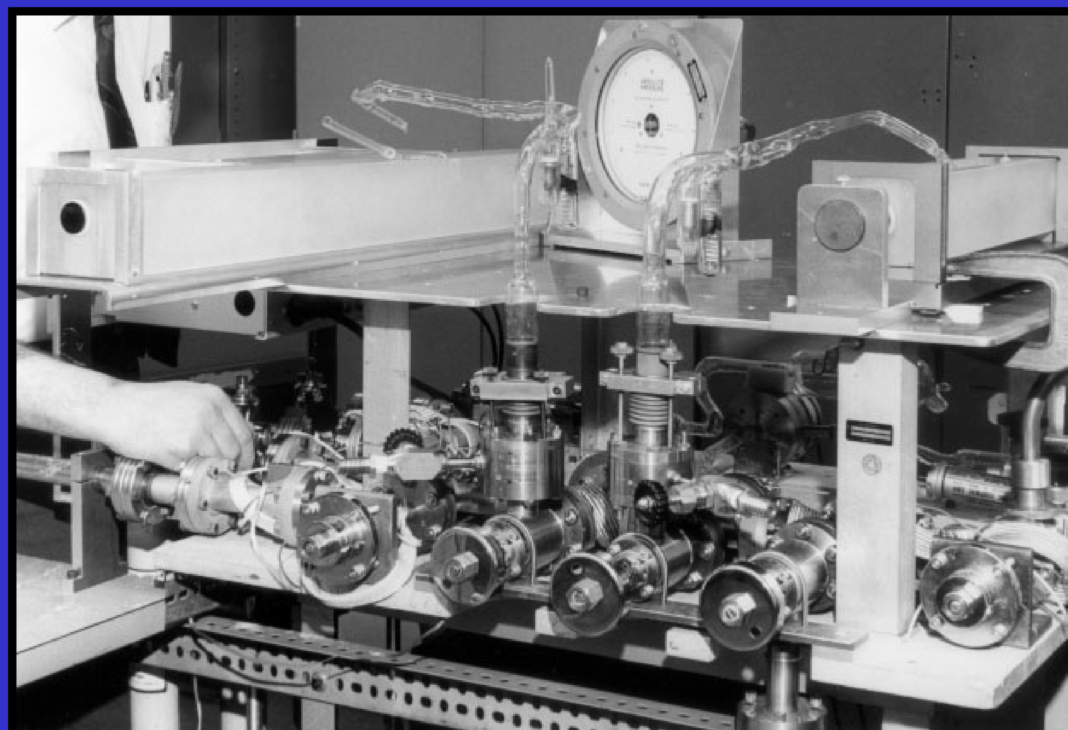
Level	Technology Readiness	Example – HG1700 Inertial Measurement Unit Guided Multiple Launch Rocket System (GMLRS)
1	Basic Principles observed and reported	**Basic research** – Invention of Gas Laser
2	Technology concept and/or application formulated.	**Basic research** – Invention of Ring Laser. Theoretical description of Ring Laser Gyro

Laser

Research

Facility

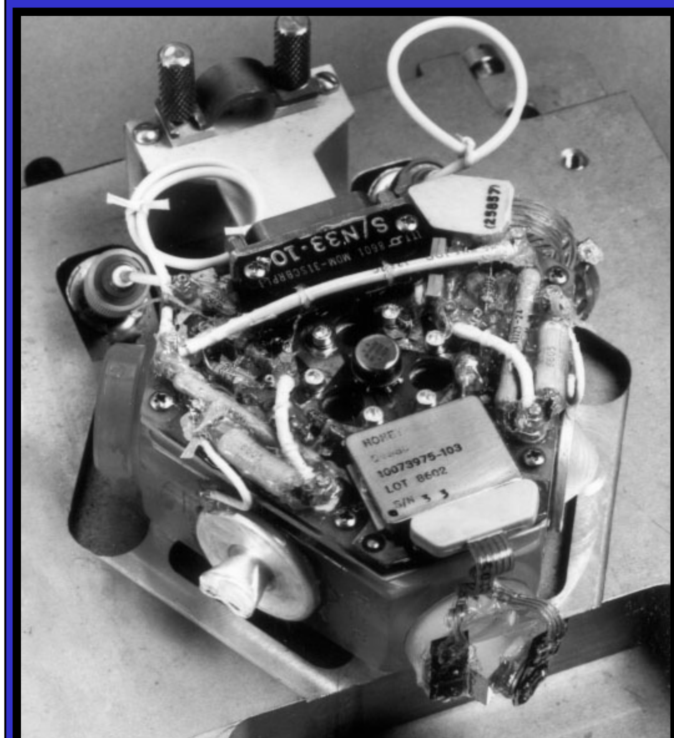
circa 1960

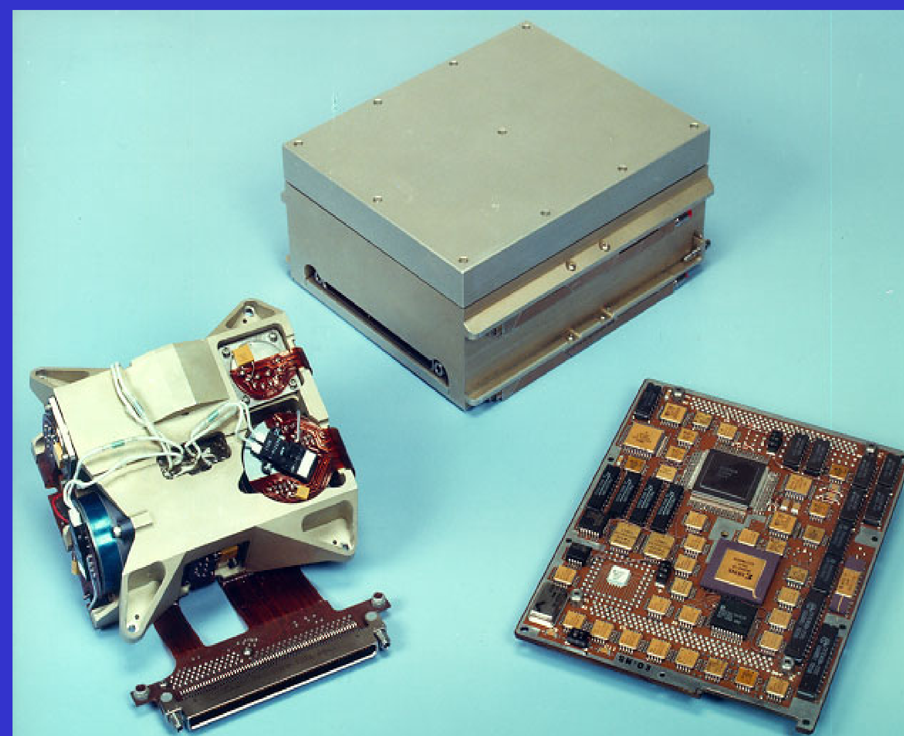


Technology Readiness Example

Level	Technology Readiness	Example – HG1700 Inertial Measurement Unit Guided Multiple Launch Rocket System (GMLRS)
3	Analytical and experimental critical function and/or characteristic proof of concept.	**Applied research** – Demonstration of Ring Laser as a rate sensor

Ring Laser Gyro circa 1975





HG1108 Inertial Measurement Unit circa 1990

Technology Readiness Example

Level	Technology Readiness	Example – HG1700 Inertial Measurement Unit Guided Multiple Launch Rocket System (GMLRS)
5	Component and/or breadboard validation in relevant environment.	**Advanced Technology Demonstration** – Demonstration of HG1700-based guidance set components (IMU, GPS receiver, control system, flight computer) in a high-fidelity hardware-in-the-loop facility

Technology Readiness Example

Level	Technology Readiness	Example – HG1700 Inertial Measurement Unit Guided Multiple Launch Rocket System (GMLRS)
6	System/subsystem model or prototype demonstrated in a relevant environment.	**Advanced Technology Demonstration** – Demonstration of actual flight-ready HG1700-based guidance set in a high-fidelity hardware-in-the-loop facility and under expected levels of shock, vibration, altitude and temperature

Technology Readiness Example

Level	Technology Readiness	Example – HG1700 Inertial Measurement Unit Guided Multiple Launch Rocket System (GMLRS)
7	System prototype demonstrated in an operational environment.	**System Design and Demonstration** – Demonstration of actual Guided MLRS missile in a flight test sequence from an operational launcher. Successful operation in multiple flight demonstrations

Advanced Technology Demonstration

GPS-aided IMU Flight
(2m miss at 49 km range)

Technology Readiness Example

Level	Technology Readiness	Example – HG1700 Inertial Measurement Unit Guided Multiple Launch Rocket System (GMLRS)
8	Actual system completed and "flight qualified" through test and demonstration.	**Low Rate Initial Production** – Developmental Test and Evaluation of GMLRS in its final form under mission conditions.
9	Actual system "flight proven" through successful mission operations.	**Production** – Operational Test and Evaluation of GMLRS by the soldier, airman, or seaman.

TECHNOLOGY STEEL READINESS LEVELS
EXAMPLE: HSLA-100 STEEL FOR AIRCRAFT CARRIER STRUCTURE
MARCH 2002

Technology Readiness Level 1:
Basic Principles Observed and Reported

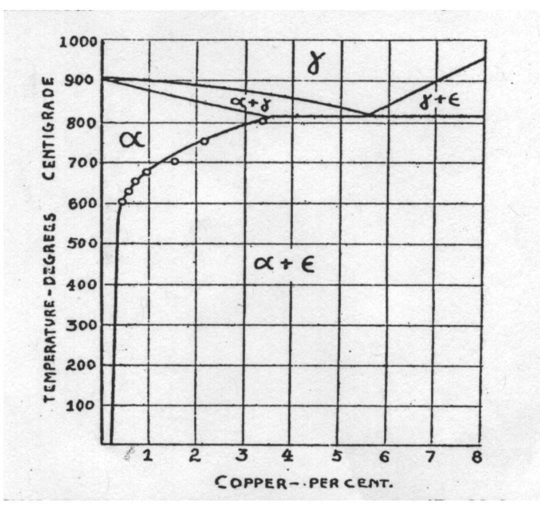
The lowest Technology Readiness Level (TRL), where scientific research begins to be translated into technology's basic properties.

With the mass industrialization of structural steel welding for shipbuilding in World War II, the quest for high-strength steels with good weldability was a motivation for metallurgical research that continued through the post-war era. Carbon strengthening and alloying that resulted in high strength was counter to weldability. The fundamental metallurgical tools for steel alloy design (e.g., phase transformation, phase diagrams, relationship of microstructure to properties, precipitation strengthening, and so forth) were developing at a dramatic rate along with the U.S. steel industry.

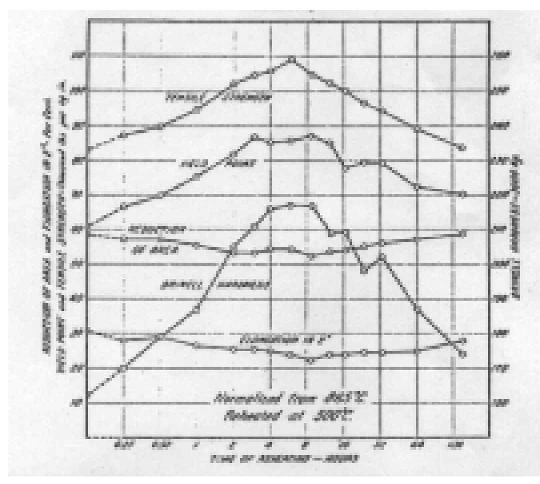
In the 1930s, the unique property of precipitation hardening induced by alloying of copper in steel was established. The phase diagrams for the Fe-Cu system were formulated, the solubility limits of Cu in low carbon steel were explored, and laboratory studies of copper steels were conducted. However, the benefit of Cu-strengthening as a means toward optimum strength, toughness, and weldability was not recognized.

Key References:

Smith, C.S. and E.W. Palmer, "The Precipitation-hardening of Copper Steels," *Trans. AIME*, Vol. 105 (1933).



Fe-Cu Phase Diagram



Precipitation Hardening in Heat Treatment of an 0.27% C, 1% Cu Steel

Technology Readiness Level 2:
Invention Begins

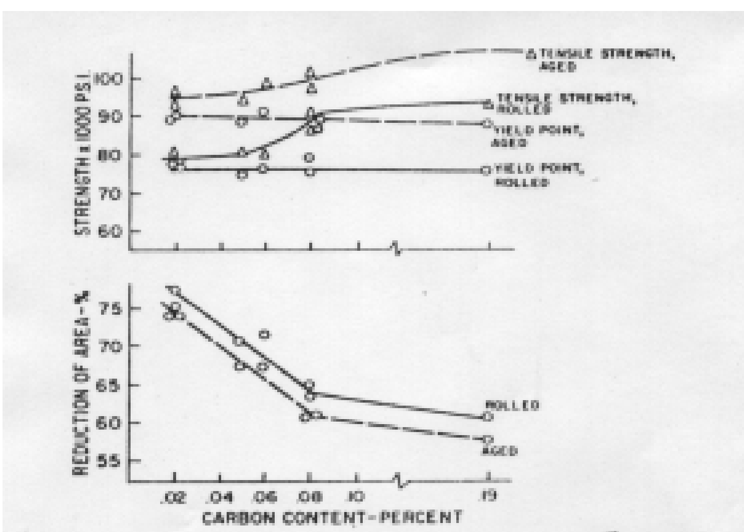
Once basic principles are observed, practical applications can be invented. However, the application is speculative, and no proof or detailed analysis exists to support the assumption.

In the mid-1960s, the laboratories of the International Nickel Company (INCO) initiated the development of a class of low-carbon, age-hardening Ni-Cu-Cb steels called "NiCuAge" steels. The work focused on the very low carbon, with changes in Ni, Cu, and Cb content and processing (hot working schedules and heat treatment) to establish microstructure-mechanical property relationships. The combinations of strength, ductility, and processing characteristics exhibited by the Ni-Cu-Cb steels suggested a variety of applications in transportation, automotive, and oil field construction. Because of the low carbon content, the steel offered excellent formability and weldability in the fully strengthened condition.

The key concepts discovered at this stage were the importance of Ni and Cb additions to the copper steels. The Ni addition and the ratio of Ni-to-Cu were established as a means to prevent cracking during hot working. Researchers discovered that small additions of Cb significantly increased strength, provided grain refinement, and did not degrade any characteristics of the steel. At this stage, small laboratory melts (30 lb) were used for the alloy composition optimization.

Key References:

Hurley, J.L. and C.H. Shelton, "Age-Hardenable Nickel-Copper Steels," *Metals Engineering Quarterly,* ASM, May 1966.



Tensile Ductility of Ni-Cu Steel as Influenced by Carbon Content

Technology Readiness Level 3: Active Research and Development (R&D) Is Initiated

This includes analytical and laboratory studies to validate physically the analytical predictions of separate elements of the technology.

INCO continued the development of improved “NiCuAge” steel for improved weldability and low-temperature toughness in heavy section plates and forgings and, in 1972, marketed the steel designated IN-787 for offshore platforms and ship hull plates. The American Society for Testing and Materials (ASTM) Standard Specification A710, Grade A, based on IN-787 steel, was issued in 1975. Armco Steel Corporation produced a plate to ASTM A710, Grade A, under the trade name “NI-COP” steel.

The primary reason for preheat in the welding of High Yield Strength (HY)-80 and HY-100 steels is to mitigate underbead cracking (hydrogen related) in the hard, martensitic heat-affected zone (HAZ). The Navy High-Strength Low-Alloy (HSLA)-80, an optimized version of ASTM A710, Grade A steel, is a ferritic steel. The microstructure of the quenched and aged HSLA-80 plate product is generally an acicular ferrite. Ferritic steels are widely used in civil construction because of their excellent weldability.

In 1981, the Navy HSLA Steels Exploratory Development Program was initiated at David Taylor Research Center (DTRC), with ASTM A710, Grade A selected as the primary candidate. Because of the positive results emanating from the project, ASTM A710, Grade A, Class 3 steel was authorized as substitute for HY-80 steel on a production trial basis in CVN 71 in selected noncritical, nonwetted areas in 1983. Upon completion of the evaluation of ASTM A710 for Navy requirements, the modifications to ASTM A710 were incorporated in MIL-S-24645(SH), 4 September 1984, for HSLA-80 steel plate, sheet, and coil. The Naval Sea Systems Command (NAVSEA) certified HSLA-80 for surface ship construction and repair in thickness up to 1-1/4 inch, 16 February 1984. The evaluation of HSLA-80 properties, welding, and structural performance demonstrated that the very-low-carbon, copper precipitation-strengthened steel met the requirements of HY-80 steel and was readily weldable with no preheat (32 °F minimum) using the same welding consumables and processes as those used for HY-80 steel fabrication. Since 1985, HSLA-80 steel has been used in CG 47 Class construction in increasing tonnage, in CVN 72 and follow-on ships, and in DDG 51 Class, LHD 1 Class, LSD 41 Class, and FFG 7 Class modifications.

Following the HSLA-80 program, a research and development (R&D) project commenced in 1985 to establish the feasibility of HSLA-100 steel as a replacement for HY-100 to reduce fabrication costs. A contract to AMAX Materials Research Center in 1985 initiated the laboratory alloy development for HSLA-100 steel. The objective for HSLA-100 was to meet the strength and toughness of HY-100 steel but to be weldable without the preheat requirements of HY-100, using the same welding consumables and processes as those used in welding HY-100. The project for the development of HSLA-100 steel in the laboratory alloy design phase used the principles of very low carbon, copper-precipitation strengthened steel successful for HSLA-80.

Fracture-process research on HSLA-80 steel indicated that a uniformly small grain size and wider distribution of small carbides would reduce the fracture transition temperature. In fact, HSLA-80 plates of 1-inch gage and less were typically a fine-grained, acicular ferrite microstructure with widely dispersed fine carbides and showed excellent low-temperature toughness. The aim of HSLA-100 alloy design was to produce a homogeneous, fine-grained, low-carbon martensite microstructure that dispersed the secondary transformation products. The alloy development effort to modify HSLA-80 steel microstructurally used laboratory-scale heats (50 to 100 lb) to study the effects of Mn, Ni, Mo, Cu, Cr, Cb, and C in hot rolled, quenched, and aged HSLA-100 plate. Laboratory plates in thicknesses of 1/4, 3/4, 1-1/4, and 2 inches of HSLA-100 exceeded the minimum strength and impact toughness requirements.

Microstructural analysis was conducted to develop composition ranges for heavy gage plate, meeting the strength and toughness requirements, where polygonal ("blocky") ferrite microstructures were not present. A regression analysis was conducted on the results for plates from 45 experimental melts to develop composition ranges for an Interim Specification for HSLA-100 Steel Plate. The Interim Specification was then used as the basis for a trial commercial production of HSLA-100 steel by domestic steel plate mills.

The copper content of HSLA-100 steel is higher than that in HSLA-80 [for additional precipitation strengthening (maximum solubility of copper in iron is near 2 percent)], and increased hardenability was achieved by increases in manganese, nickel, and molybdenum. Nickel, the greatest increase over that in HSLA-80, lowers upper shelf impact toughness but also lowers (improves) the impact toughness transition temperature. The microstructure of HSLA-100 steel was identified by optical and scanning electron microscopy as low-carbon martensite or a granular, low-carbon bainite, depending on plate gage—a significantly different metallurgy and microstructure than the ferritic HSLA-80 steel microstructures.

Key References:

Certification of HSLA-80 Steel, NAVSEA ltr 05MB/BPS, Ser 5, dated 16 February 1984.

Coldren, A.P. and T.B. Cox, *Development of 100 Ksi Yield Strength HSLA Steel,* DTNSRDC-CR-07-86, July 1986.

Coldren, A.P., T.B. Cox, E.G. Hamburg, C.R. Roper, and A.D. Wilson, *Modification of HSLA-80 Steel to Improve Toughness in Heavy Sections,* DTRC Report SME-CR-04-91, February 1991.

Jesseman, R.J. and G.C. Schmid, "Submerged Arc Welding a Low-Carbon, Copper Strengthened Alloy Steel," *Welding Journal Research Supplement*, Vol. 62, No. 11, November 1983, pp. 321s–330s.

Jesseman, R.J. and G.J. Murphy, "Mechanical Properties and Precipitation Hardening Response in ASTM A710 Grade A and A736 Alloy Steel Plates," *Journal of Heat Treating*, Vol. 3, No. 3, June 1984, pp. 228–236.

Kvidahl, L.G., "An Improved High Yield Strength Steel for Shipbuilding," *Welding Journal*, Vol. 64, No. 7, July 1985, pp. 42–48.

McCaw, R.L. and R.J. Wong, *Welding of HSLA-80 Steel,* DTNSRDC/SME-85/32, June 1985.

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Montemarano, T.W., R.T. Brenna, T.E. Caton, D.A. Davis, R.L. McCaw, L.J. Roberson, T.M. Scoonover, and R.J. Wong, *Results of the Evaluation of ASTM A710, Grade A Steel Under the "Certification of HSLA Steels for Surface Ship Construction Program,"* DTNSRDC TM-28-84-17, January 1984.

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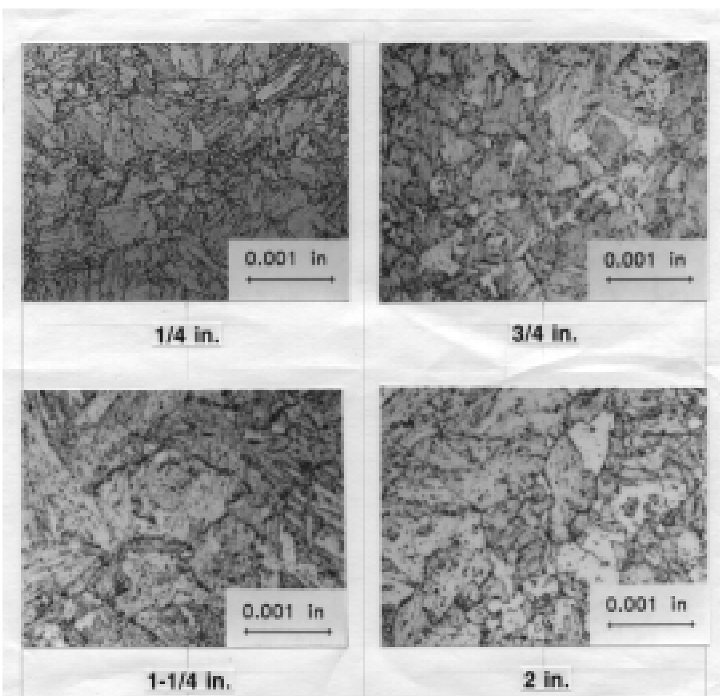
Wilson, A.D., "High Strength, Weldable Precipitation Aged Steels," *Journal of Metals*, March 1987, pp. 36–38.



Experimental HSLA-100 Steel Plate Microstructures for a Range of Plate Thickness

Technology Readiness Level 4: Basic Technology Components Are Integrated

The basic components of the technology are integrated to establish that the pieces will work together.

For the trial plate production phase of the HSLA-100 steel project, an initial 150-ton production of HSLA-100 steel was melted and rolled by Phoenix Steel Corporation in 1986 to the interim specification, using conventional electric furnace and ingot casting practice, conducted to achieve a very-low-carbon composition. The minimum strength and toughness requirements of the interim specification were met in the initial production of HSLA-100 steel plate in gages from 1/4 to 2 inches. Optimum properties in HSLA-100 plate resulted from aging temperatures from 1150 to 1275 ºF.

Upon receipt of HSLA-100 plate from the trial productions, an evaluation commenced to evaluate HSLA-100 steel plate and welding using the processes and procedures for HY-100 steel ship and submarine structural applications—but with reduced or no preheat. The evaluation of HSLA-100 steel plate properties and welding demonstrated that HSLA-100 steel met the mechanical property requirements of HY-100 steel and was weldable with reduced preheat requirements, using the same welding consumables as for HY-100 steel fabrication. When compared with HY-100 steel, the tensile and impact toughness properties of the plates met or exceeded the requirements.

The primary reason for preheating when welding the HY-series steels was to mitigate underbead cracking (hydrogen related) in the HAZ. The HSLA-100 precertification evaluation emphasized welding and weldability testing to demonstrate that HSLA-100 was more resistant to hydrogen cracking than HY-100 (to allow a relaxation of preheat requirements). The findings of the HSLA-100 steel welding and weldability evaluations are summarized as follows:

- The strength and toughness of weld metals deposited by the Shielded Metal Arc Welding (SMAW), Submerged Arc Welding (SAW), Pulsed Gas Metal Arc Welding (GMAW-P), and Short Circuiting Gas Metal Arc Welding (GMAW-S) processes, using the welding consumables qualified for HY-100 welding, met the requirements when welded over a broader range of operating conditions (heat inputs ranging from 22 to 65 kJ/in.) than for HY-100. No "hard" microstructures were indicated, and the Charpy V-notch toughness of the HAZ in HSLA-100 weldments was equal to or greater than the weld metal toughness.
- It was demonstrated that HSLA-100 fillet weld strengths were equivalent to HY-100 welds using the same process, filler metal, and fillet size.
- HSLA-100 plate, weld metal, and weld HAZ did not show any susceptibility to stress corrosion cracking exposed at –1,000 mV at or above stress corrosion cracking threshold stress intensity values determined for HY-100, MIL-100S-1, and MIL-120S-1 weld metals.

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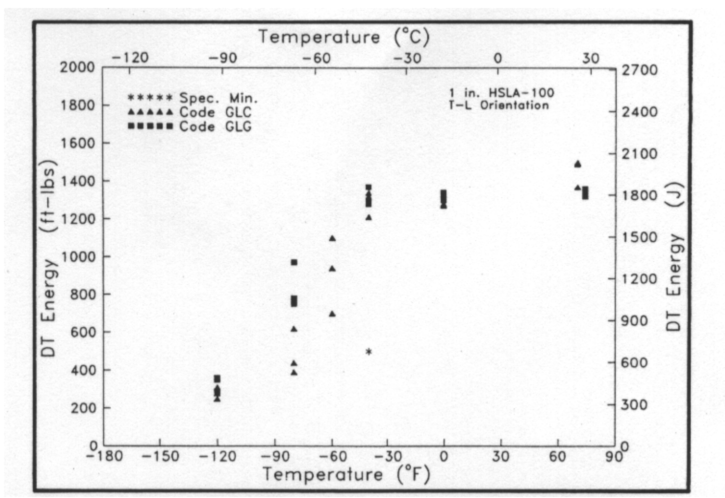
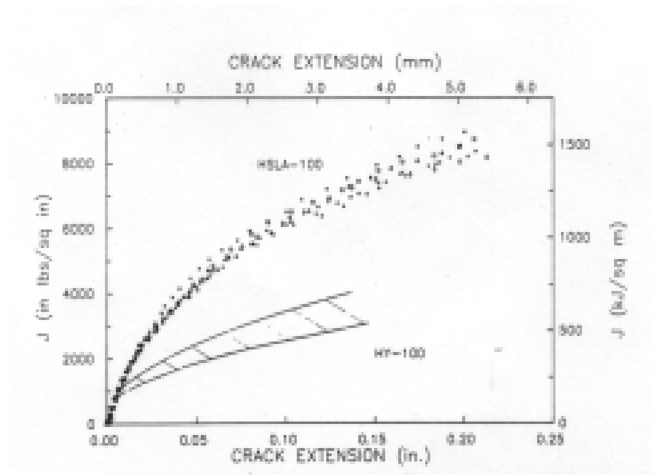
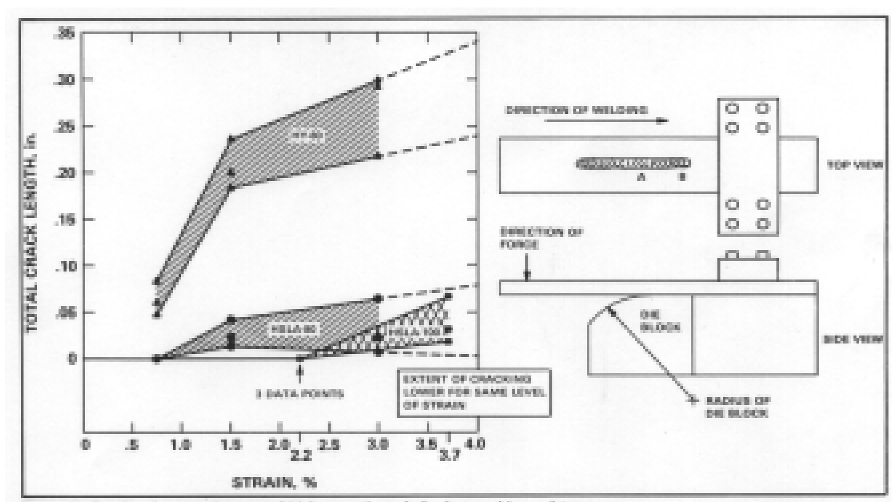


Dynamic Tear Test Results for HSLA-100 Steel Plates



Fracture Toughness Test Results of HSLA-100 and HY-100



Varestraint Weldability Tests of High-Strength Steels

Technology Readiness Level 5: Technology Sufficiently Advanced For Simulation Tests

The fidelity of breadboard technology increases significantly enough to justify being ready for testing in a simulated environment.

Lukens Steel Company produced a second melt of HSLA-100 steel, again by electric furnace and ingot casting. Most of the plate produced from the heat was greater than 2 inches thick, primarily for ballistic resistance evaluation. The minimum strength and toughness requirements were met in plate thicknesses from 1/2 to 3-3/4 inches. A double austenitization and quench process was used for HSLA-100 steel plate in gages over 1-1/4 inches to refine the heavy-plate grain structure for optimum toughness. HSLA-100 plate from both productions to the interim specification was the primary material used in the certification program.

The certification evaluation included continued characterization of production HSLA-100 steel plate mechanical, physical, and fracture properties. However, the main focus was the evaluation of weldability and welding process limits for structures of high restraint, studies of fatigue properties, and effects of marine environments on HSLA-100.

The results of low-cycle fatigue crack initiation tests of HSLA-100 steel and weldments and high-cycle fatigue tests in air and seawater showed properties equivalent to HY-100 steel in every case. The steels showed similar fatigue crack growth rate properties. General corrosion, crevice corrosion, galvanic corrosion, and high-velocity seawater parallel flow and cavitation tests of HSLA-100 in seawater showed that the corrosion behavior of HY-100 and HSLA-100 steels was comparable.

Key References:

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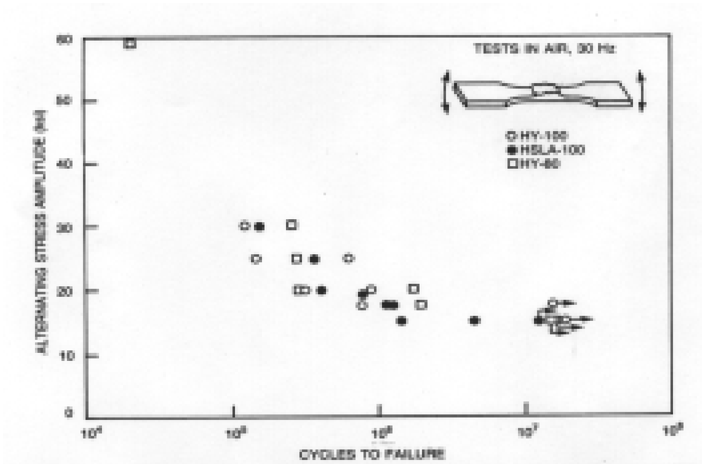
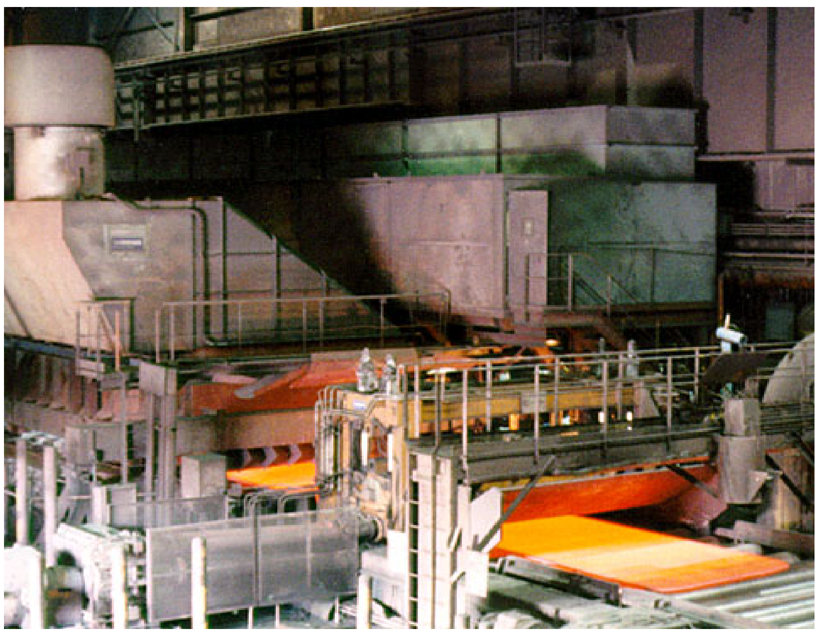
Werchniak, W., E.J. Czyryca, and D.M. Montiel, *Fatigue Properties of HSLA-100 Steel and Weldments*, DTRC/SME-89/113, September 1990.

Fatigue Test Results for HSLA-100, HY-100, and HY-80 Steel Weldments





Technology Readiness Level 6: Model/Prototype Tests

Representative model or prototype system, which is well beyond the breadboard tested at TRL 5 and is tested in a relevant environment.

The evaluation of HSLA-100 steel production plates concluded that the mechanical properties of production plate, welding and weldability screening tests, fatigue properties, and corrosion properties demonstrated that the system was viable for certification for combatant ship structure. Evaluation as a system by explosion bulge and crack-starter bulge tests, fragment penetration resistance tests, and ballistic property tests was demonstrated in the next phase.

Explosion bulge and crack starter explosion bulge tests of 2-inch thick weldments by GMAW, SMAW, and SAW of HSLA-100 steel were successfully conducted. The weldments were fabricated within the recommended preheat/interpass temperatures expected for HSLA-100 fabrication, exhibited no indications of hydrogen damage, and passed the explosion bulge test requirements.

In 1987, NAVSEA initiated projects at Electric Boat Corporation and Newport News Shipbuilding (NNS) to evaluate the weldability of HSLA-100 steel under various preheat conditions in a production environment. The results of the weldability evaluation demonstrated that HSLA-100 steel could be welded at up to 1.25-inch thick at 60 °F minimum preheat, with the same processes and consumables being used for HY-80/100 steels.

Based on NNS' welding and weldability evaluations of HSLA-100 using HY-100 welding consumables, welding preheat/interpass temperature limits were established. Preheat was recommended for SAW and SMAW, based on the weld metal cracking tendencies noted for these flux-assisted processes in the weldability testing. For GMAW and SAW, difficulties were experienced in obtaining MIL-100S-2 and MIL-120S-2 wire electrodes (low hydrogen content) with acceptable wire-feed characteristics for elimination of preheat for heavy-gage plate welding. Research projects are in progress to develop welding consumables specifically for HSLA-100 to achieve preheat-free welding in heavy plate, highly restrained welds.

Ballistic evaluations demonstrated that HSLA-100 steel and GMAW (MIL-100S-1) weldments (fabricated without preheat) were equivalent to HY-100 steel and weldments in ballistic resistance. Both steels were comparable to Army Rolled Homogeneous Armor.

NNS completed weld qualification and weldability testing to conduct pulsed-arc GMAW and SAW of HSLA-100 in thicknesses greater than 1 inch through 1-5/8 inch at 60 °F preheat using MIL-100S-2 electrode. NAVSEA approved the procedures. It should also be noted that Ingalls Shipbuilding Division (ISD) conducted weld qualification and weldability tests of HSLA-100 up to 1-inch gage using both HY-100- and HY-80-type welding consumables and processes.

The present material specification for HSLA-80 and HSLA-100 steel strip, sheet, and plate is MIL-S-24645A, with Amendment 1 of 24 September 1990. HSLA-100 was

certified by NAVSEA for surface ship construction in thicknesses up to 4 inches, 13 March 1989.

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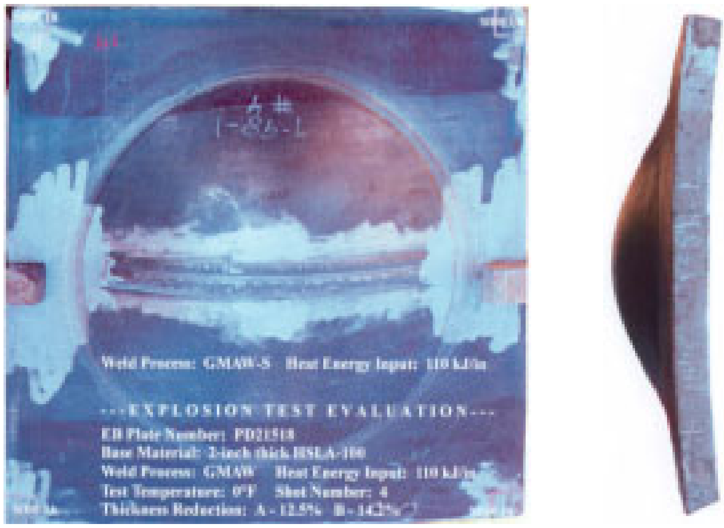
Wallace, D.T., *HSLA-100 Weldability Tests for CVN-73 Material Substitution for HY-100 Steel,* Newport News Shipbuilding and Drydock Company, Report No. E.80 (S11D)-1, Contract No. N00024-88-C- 2044, February 1989.



Explosion Bulge Test of HSLA-100 2-inch Thick Weldment

Fragment Penetration Resistance HSLA-100 Test Weldment

Technology Readiness Level 7: Prototype Near or at Planned Operational System

TRL-7 is a major step from TRL 6, requiring the demonstration of an actual prototype in an operational environment.

The fabrication of a series of structural performance models was completed under shipyard welding conditions. Holding bulkhead panel models, foundation models, and a full-scale foundation were evaluated and demonstrated satisfactory structural performance.

The Electric Boat Division [General Dynamics Corporation] fabricated the full-scale foundation and a small, heavy-gage tank model. NNS partially completed the fabrication of a full-scale hard tank; however, a funding shortage precluded tests. In these shipyard fabrication exercises, all weld cracking was related to SMAW and SAW consumables (where cracking occurred even when HY-100 preheat temperatures were used) or to improper welding practices. No HAZ cracking occurred in HSLA-100.

Hydrostatic tests of full-gage bulkhead panel models are an extreme test of plating-to-stiffener strength and HAZ ductility. The HSLA-100 panel models exceeded anticipated holding pressure levels, withstanding over twice the holding pressure of identical HY-100 panel models. A series of foundation beam elements (full-scale) and the full-scale SSN 688-type AC foundation were installed and tested on a floating shock platform. The structures were subjected to a series of underwater explosion (UNDEX) shock tests. For a series of 3 UNDEX events, the structural response of the HSLA-100 items indicated no cracking or excessive deformation in any structural joint.

Key References:

Czyryca, E.J., *Assessment of HSLA-80 and HSLA-100 Steels for Submarine Non-Pressure Hull Applications,* CARDIVNSWC-TR-61-94/38, Preliminary, February 1995.

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Spaulding, R.S., P.D. Thomas, and R.A. Spitzer, *HSLA-100 Hard Tank Fabrication and Fatigue Model, Design and Fabrication Report,* Newport News Shipbuilding and Drydock Company, Report G2001- 0059, Contract No. N00024-87-C-2012, 9 September 1988.

Thomas, P.D., *HSLA-100 Hard Tank Fabrication and Fatigue Model Construction,* Newport News Shipbuilding and Drydock Company, Report No. ES10-1, Contract No. 00024-85-C-2056, 29 July 1988.

HSLA-100 Steel/LC-100 Weld Metal
Box-Tank Fatigue Model
Overall View of Model Exterior/End Hatch Open

HSLA-100 Holding Bulkhead Panel Model:
Before Test (Left) and After Hydrostatic Test to Rupture (Right)

Technology Readiness Level 8:
Technology Demonstrated In Operation

Technology has been proven to work in its final form and under expected conditions.

In 1989, NAVSEA certified HSLA-100 steel for surface ship construction in thicknesses up to 4 inches. At that time, the *USS JOHN C. STENNIS* (CVN 74) was approved, indicating that HSLA-100 steel was a qualified substitute for HY-80/100 steel in CVN construction. Fabrication was to be conducted in accordance with MIL-STD-1689A(SH), *Fabrication, Welding, and Inspection of Ships Structure*. The experience base for welding HSLA-100 steel was too limited to allow the wholesale substitution for all HY-80/100 steel in the unrestricted areas of the carrier. Therefore, an implementation plan for incorporation was submitted, and NAVSEA approved this plan.

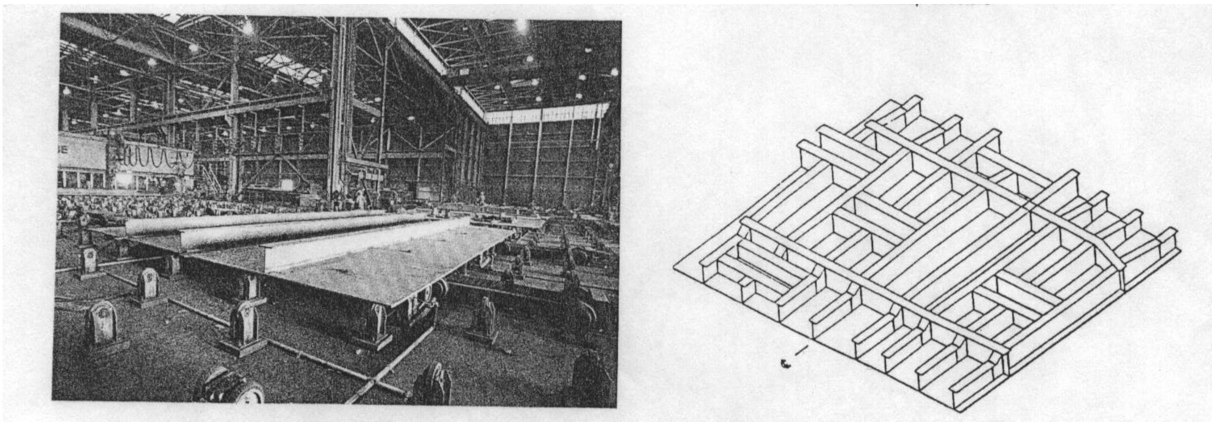
The CVN 74 main deck was the chosen area for HSLA-100, and approximately 770 LT were earmarked. The thicknesses in this area were 7/8-inch and 1-inch thick HSLA-100. The fabrication results were excellent. A total of 16,656 inches of butt joints in the 7/8-inch plate were welded, with only 8 inches requiring repair. In the 1-inch plate, 16,524 inches of butt joints were welded, and no defects were found. Since the ship was under construction at the time of the implementation plan, the total tonnage inserted into CVN 74 was limited to 1,250 LT, mostly above main deck.

NNS used HSLA-100 steel during CVN 74 construction. Approximately 700 tons of HSLA-100 steel plate in 7/8- and 1-inch thicknesses were used for main deck panel assemblies with longitudinal and transverse stiffeners without preheat (65 to 80 °F shop temperature). One hundred percent magnetic particle inspection was performed on all HSLA-100 butt welds. In 1,400 feet of 7/8-inch thick HSLA-100 butt weld inspected by MT, only 2 repairs (8 inches total) were required, not related to hydrogen-type defects. The same length of 1-inch thick HSLA-100 butt weld inspected by magnetic particle inspection showed no defects. A total of 1,250 tons of HSLA-100 were used in CVN 74, with over 4,000 feet of weldment inspection requiring 32 inches total repair (less than 0.01 percent).

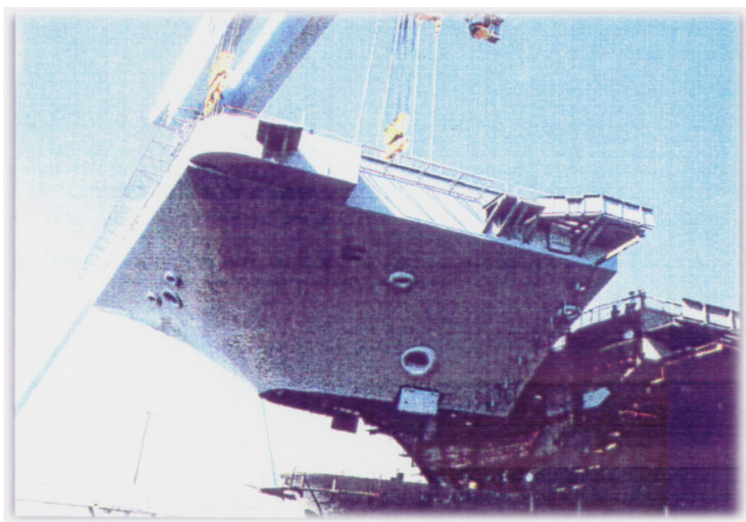
NNS completed weld qualification and weldability testing to conduct pulsed-arc GMAW and SAW of HSLA-100 in thicknesses greater than 1 inch through 1-5/8 inch at 60 °F preheat using MIL-100S-2 electrode. NAVSEA approved the procedures. It should also be noted that ISD conducted weld qualification and weldability tests of HSLA-100 up to 1-inch gage using both HY-100- and HY-80-type welding consumables and processes. The flight deck of the *USS BATAAN* (LHD 5) was successfully fabricated with HSLA-100 plate (in place of HY-100 steel) for cost savings, as were subsequent vessels of the same class.

Key References:

Christein, J.P. and J.L. Warren, "Implementation of HSLA-100 Steel in Aircraft Carrier Construction - CVN 74," *Journal of Ship Production*, Society of Naval Architects and Marine Engineers, 1994.



CVN 74 HSLA-100 Steel Main Deck Panel Fabrication



Technology Readiness Level 9:
Implementation of the Technology in Service

Actual application of the technology in its final form and under mission conditions.

Because of the experience gained on CVN 74, wholesale changes to HSLA-100 were made on CVN 75. Approximately, 10,500 LT of HSLA-100 were inserted into CVN 75. Most of the replacement was for decks and bulkheads and some built-up stiffeners. The HSLA-100 stiffeners were short spans with heavy web/flange members. HSLA-100 steel was selected to replace HY-100 for fabrication cost reduction, and, as a consequence, HSLA-100 steel has been used in place of HY-100 in the construction of *USS JOHN C. STENNIS* (CVN 74), *USS HARRY S. TRUMAN* (CVN 75), and *USS RONALD REAGAN* (CVN 76).

On CVN 76, NAVSEA 08 approved the substitution of HSLA-100 for HY-80/100 structures outside the primary shield tank, opening another area for substitution. On CVN 77, expended use of HSLA-100 plate continues. NNS expects to qualify reduced preheat for welding up to 2 inches, adding over 4,000 LT of HSLA-100 where significant fabrication cost reduction is gained over HY-100 in this thickness range. Depending on complexity of the structure, estimated cost savings, for HSLA-100 vs. HY-100 fabrication in CVN 74 construction range from $500 to $3,000 per ton of fabricated structure.

The table below summarizes the tonnage of HSLA-100 steel plate used to date in construction of U.S. Navy combatant ships. The continued expansion of the use of HSLA-100 steel is planned for CVNX (CVN 78) design, including the heavy plating and foundation in the propulsion area.

Class	Vessels	LT
CVN 68	CVN 74	2,080
	CVN 75	11,600
	CVN 76	12,500
	CVN 77	12,500
LHD 1	LHD 5	1,180
	LHD 6	1,200

ACRONYMS AND ABBREVIATIONS FOR APPENDIX D[8]

ASM	American Society for Metals International
ASTM	American Society for Testing and Materials
CG	Carrier Group
CVN	Aircraft Carrier, Nuclear
CVNX	Aircraft Carrier, Nuclear, Experimental
DDG	Guided Missile Destroyer
DTNSRDC	David Taylor Naval Ships Research and Development Center
DTRC	David Taylor Research Center
FFG	Guided Missile Frigate
GMAW-P	Pulsed Gas Metal Arc Welding
GMAW-S	Short Circuiting Gas Metal Arc Welding
GMLRS	Guided Multiple Launch Rocket System
HAZ	heat-affected zone
HSLA	High-Strength Low-Alloy
HY	High Yield Strength (steel)
IMU	Inertial measurement Unit
INCO	International Nickel Company
ISD	Ingalls Shipbuilding Division
LHD	Amphibious Assault Ship
LSD	Dock Landing Ship
LT	long ton
NAVSEA	Naval Sea Systems Command
NNS	Newport News Shipbuilding
OTC	Offshore Technology Conference
RLG	Ring Laser Gyro
SAW	Submerged Arc Welding
SMAW	Shielded Metal Arc Welding
SME	Society for Mining, Metallurgy, and Exploration
TM	Technical Manual
TRL	Technology Readiness Level
UNDEX	underwater explosion

[8] These acronyms are for Appendix D (pp. D-1 through D-32).

APPENDIX E
SOFTWARE-SPECIFIC DEFINITIONS AND DESCRIPTIONS OF TECHNOLOGY READINESS LEVELS (TRLs)

APPENDIX E
SOFTWARE-SPECIFIC DEFINITIONS AND DESCRIPTIONS OF TECHNOLOGY READINESS LEVELS (TRLs)

When considering the maturity of developing software, U. S. Army technologists determined that they would benefit by more specific and directly relevant TRLs than the basic ones provided in the original Department of Defense (DoD) 5000 series documents. Accordingly, these Army technologists developed a software-appropriate set of TRL definitions and descriptions, which are provided in Table E-1 for reference and potential use.

Table E-1. Software TRL Definitions

TRL	Definition	Description
1	**SW**: Functionality conjectural	Lowest level of software readiness. Basic research begins to be translated into applied research and development. Examples might include a concept that can be implemented in software or analytic studies of an algorithm's basic properties.
2	**SW**: Technology concept and/or application formulated	Invention begins. Once basic principles are observed, practical applications can be invented. Applications may be speculative and there may be no proof or detailed analysis to support the assumptions. Examples are limited to analytic studies.
3	**SW**: Analytical and experimental critical functions and/or characteristic proof of concept	Active research and development is initiated. This includes analytical studies to produce code that validates analytical predictions of separate software elements. Examples include software components that are not yet integrated or representative but satisfy an operational need. Algorithms run on a surrogate processor in a laboratory environment.

Table E-1. Software TRL Definitions (Continued)

TRL	Definition	Description
4	**SW:** Functionality demonstrated in a laboratory environment	Basic software components are integrated to establish that they will work together. They are relatively primitive with regard to efficiency and reliability compared with the eventual system. System software architecture development initiated to include interoperability, reliability, maintainability, extensibility, scalability, and security issues. Software integrated with simulated current/ legacy elements as appropriate.
5	**SW:** Functionality and performance demonstrated in a relevant environment	Reliability of software ensemble increases significantly. The basic software components are integrated with reasonably realistic supporting elements so that it can be tested in a simulated environment. Examples include "high-fidelity" laboratory integration of software components. System software architecture established. Algorithms run on a processor(s) with characteristics expected in the operational environment. Software releases are "Alpha" versions and configuration control initiated. Verification, Validation, and Accreditation (VV&A) initiated.
6	**SW:** Functionality and performance demonstrated in a realistic simulated (live/virtual) operational environment	Representative model or prototype system, which is well beyond that of TRL 5, is tested in a relevant environment. Represents a major step up in software-demonstrated readiness. Examples include testing a prototype in a live/virtual experiment or in simulated operational environment. Algorithm run on processor or operational environment integrated with actual external entities. Software releases are "Beta" versions and are configuration controlled. Software support structure in development. VV&A in process.
7	**SW:** Functionality and performance demonstrated in an operational test environment.	Represents a major step up from TRL 6, requiring the demonstration of an actual system prototype in an operational environment, such as in a command post or air/ground vehicle. Algorithms run on processor of the operational environment integrated with actual external entities. Software support structure in place. Software releases are in distinct versions. Frequency and severity of software deficiency reports do not significantly degrade functionality or performance. VV&A completed.

Table E-1. Software TRL Definitions (Continued)

TRL	Definition	Description
8	**SW:** Functionality, performance, and quality attributes validated in an operational environment.	Software has been demonstrated to work in its final form and under expected conditions. In most cases, this TRL represents the end of system development. Examples include test and evaluation of the software in its intended system to determine if it meets design specifications. Software releases are production versions and are configuration controlled in a secure environment. Software deficiencies are rapidly resolved through support structure.
9	**SW:** Functionality, performance and quality attributes proven in an operational environment through successive successful accomplishment of mission operations.	Actual application of the software in its final form and under mission conditions, such as those encountered in operational test and evaluation. In almost all cases, this is the end of the last "bug fixing" aspects of system development. Examples include using the system under operational mission conditions. Software releases are production versions and are configuration controlled. Frequency and severity of software deficiencies are at a minimum

ACRONYMS AND ABBREVIATIONS FOR APPENDIX E

DoD	Department of Defense
TRL	Technology Readiness Level
VV&A	Verification, Validation, and Accreditation

APPENDIX F
BIOMEDICAL TECHNOLOGY READINESS LEVELS (TRLs)

APPENDIX F
BIOMEDICAL TECHNOLOGY READINESS LEVELS (TRLs)

Medical-related items require TRL definitions and descriptions appropriate to the technologies upon which they are based and that account for the statutes and regulations that govern their development and use. In recognition of these factors, the U.S. Army Medical R&D Command took the initiative to establish appropriate definitions, descriptions, and processes in the context of military medical R&D and the statutory and regulatory requirements under the stewardship of the Food and Drug Administration (FDA). The excellent result of their effort is provided in this appendix, with slight editing of presentation (but not substance) to suit this deskbook.

Biomedical Technology Readiness Levels (TRLs)

A. BACKGROUND

Department of Defense (DoD) policy mandates the use of U.S. Food and Drug Administration (FDA)-approved products for force health protection,[12] and the U.S. Army Medical Research and Materiel Command (USAMRMC) has always adhered to the regulatory requirements of the FDA regarding its studies of drugs, biologics, and devices in humans. To ensure compliance with the clinical phases of the FDA-regulated process and to reduce technological risk, the USAMRMC developed and recently updated their general guidelines for assigning TRLs to drug, vaccine, and medical device development programs.[13]

These guidelines are not considered absolutes, and characterization of activities associated with TRLs can and does vary at times. The science and technology (S&T) and acquisition program managers (PMs) work together in exercising discretion in the selection, progression, and timing of specific activities to be accomplished in the attainment of particular TRLs. Such flexibility and tailoring are needed to align the TRL decision criteria appropriately with the maturation and risk characteristics of a particular technology, including consideration of the associated investment strategy and transition procedures that may vary among PMs.

The lower a critical technology's TRL when transitioning from technology development to product development, the greater the risks. For medical technologies, risk reduction is not linear across TRLs. The rate of risk reduction remains very low until very late. Historically, FDA-regulated products, such as vaccines, do not achieve significant risk reduction (i.e., greater than 50 percent) until completion of Phase 3 clinical trials and approval of a biologics license application by the FDA (TRL 8). Industry experience is that only one in four vaccines going into Phase 3 trials is licensed. Similarly, whereas technology maturation is commonly perceived as a sequential continuum of activities from basic research, through development, to production and deployment, the evolution of the TRL for a critical technology may not be sequential, especially in those cases

[12] For example, Department of Defense Directive (DoDD) 6200.2, August 1, 2000, or Health Affairs Policy 95-011, July 26, 1995.

[13] *Biomedical Technology Readiness Levels (TRLs)*, prepared for the Commander, U.S. Army Medical Research and Materiel Command, under Contract number DAMD17-98-D-0022, Science Applications International Corporation, 3 June 2003.

where FDA anchors are undefined. In cases of success or failure, the incremental change in the level of technology readiness may be greater than a single TRL. For example, upon successful completion of a pivotal study, biomedical information technology readiness may move from TRL 3 or 4 to TRL 9.

Biomedical TRL descriptions provide a systematic way for the S&T community to assess and communicate to the MDA the level of maturity of a particular technology or combination of technologies as they relate to the particular category and the maturity necessary for successful product development. This appendix provides equivalent TRL descriptions applicable to biomedical technologies in four categories:

1. Pharmaceutical (i.e., drugs)
2. Pharmaceutical (i.e., biologics/vaccines)
3. Medical Devices
4. Medical Information Management/Information Technology (IM/IT) and Medical Informatics.

The TRLs for the first three categories have been developed from the DoD's generic definitions, the applicable FDA regulatory process, and industry practices and experience with its research and development (R&D) processes (discovery through manufacturing, production, and marketing). The last category includes elements of formal regulatory processes and logical events in deriving comparable levels of maturity. The USAMRMC intends to use external anchors such as "FDA events" wherever practical to define each TRL decision criterion. Furthermore, activities described as occurring between successive TRL decision criteria are intended to exemplify the kinds of activities that routinely take place when maturation is sequential and stepwise. However, these examples are neither mandatory nor all-inclusive.

Figure I-1 and Table I-1 build upon this work by providing examples of supporting information and documentation required to support the assignment of TRLs as the program progresses.

In addition, a description of the FDA regulatory process, points of contact (POCs) within FDA, sources of additional information, a glossary of terms, and a list of acronyms and abbreviations are provided.

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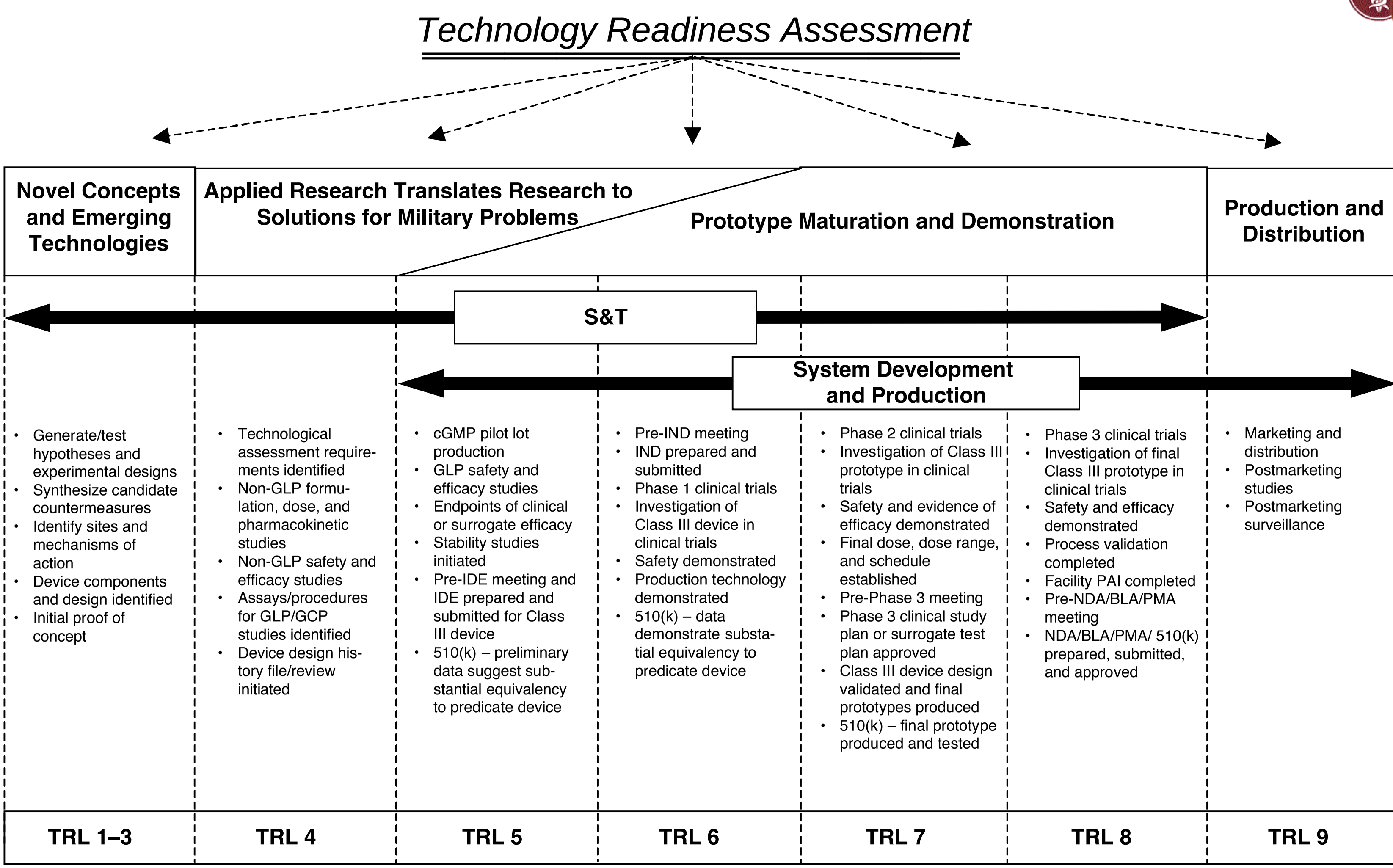

Figure I-1. TRLs in the Medical Materiel Regulatory Process

Note for Figure I-1: *The TRL descriptions are not considered absolutes, and characterization of activities associated with TRLs can and does vary at times. The S&T and Acquisition PMs work together in exercising discretion in the selection, progression, and timing of specific activities to be accomplished, particularly with regard to TRL 5. Such flexibility and tailoring are needed to align the TRL decision criteria appropriately with maturation and risk characteristics of a particular technology, including consideration of the associated investment strategy and transition procedures that may vary among PMs.*

General Note for Table I-1: *The N1, N2, N3, and N4 superscripts refer to the Notes that are listed at the end of Table I-1.*

Table I-1. Proposed TRLs for Medical Research, Development, Test, and Evaluation (RDT&E)

TRL 1 NASA/*Interim Guidebook*[14] TRL Definition: Basic principles observed and reported

NASA/ *Interim Guidebook* TRL Description	***USAMRMC Equivalent TRL Descriptions***			
	Pharmaceutical (Drugs) TRL Description[N1, N2]	**Pharmaceutical (Biologics, Vaccines) TRL Description[N1, N2]**	**Medical Devices TRL Description [N3, N4]**	**Medical IM/IT & Medical Informatics**
Lowest level of technology readiness. Scientific research begins to be translated into applied research and development. Examples might include paper studies of a technology's basic properties.	Lowest level of technology readiness. Maintenance of scientific awareness and generation of scientific and bioengineering knowledge base. Scientific findings are reviewed and assessed as a foundation for characterizing new technologies. **TRL 1 Decision Criterion:** Scientific literature reviews and initial market surveys are initiated and assessed. Potential scientific application to defined problems is articulated.	Lowest level of technology readiness. Maintenance of scientific awareness and generation of scientific and bioengineering knowledge base. Scientific findings are reviewed and assessed as a foundation for characterizing new technologies. **TRL 1 Decision Criterion:** Scientific literature reviews and initial market surveys are initiated and assessed. Potential scientific application to defined problems is articulated.	Lowest level of technology readiness. Maintenance of scientific awareness and generation of scientific and bioengineering knowledge base. Scientific findings are reviewed and assessed as a foundation for characterizing new technologies. **TRL 1 Decision Criterion:** Scientific literature reviews and initial market surveys are initiated and assessed. Potential scientific application to defined problems is articulated.	HW/SW system technology explored. Basic theories applied to IM/IT field suggesting promise. **TRL 1 Decision Criterion:** Identification of the potential medical solution to mission need. Medical Informatics data and knowledge representation issues are defined.
	Supporting Information	**Supporting Information**	**Supporting Information**	
	Reviews of open, published scientific literature concerning basic principles. Findings from market surveys of the open literature. **Note:** *Privately funded research findings or market surveys are proprietary and rarely available to the public.*	Reviews of open, published scientific literature concerning basic principles. Findings from market surveys of the open literature. **Note:** *Privately funded research findings or market surveys are proprietary and rarely available to the public.*	Reviews of open, published scientific literature concerning basic principles. Findings from market surveys of the open literature **Note:** *Privately funded research findings or market surveys are proprietary and rarely available to the public.*	

[14] *Interim Defense Acquisition Guidebook (Interim Guidebook)*, dated October 30, 2002. This *Interim Guidebook* (formerly the DoD 5000.2-R, dated April 5, 2002) contains nonmandatory guidance on best practices, lessons learned, and expectations. It is anticipated that the *Interim Guidebook* will be revised in the near future.

Table I-1. Proposed TRLs for Medical (RDT&E) (Continued)

TRL 2 **NASA/*Interim Guidebook* TRL Definition:** Technology concept and/or application formulated				
NASA/ *Interim Guidebook* TRL Description	***USAMRMC Equivalent TRL Descriptions***			
	Pharmaceutical (Drugs) TRL Description[N1, N2]	**Pharmaceutical (Biologics, Vaccines) TRL Description**[N1, N2]	**Medical Devices TRL Description** [N3, N4]	**Medical IM/IT & Medical Informatics**
Invention begins. Once basic principles are observed, practical applications can be invented. Applications are speculative, and there may be no proof or detailed analysis to support the assumptions. Examples are limited to analytic studies.	Intense intellectual focus on the problem, with generation of scientific "paper studies" that review and generate research ideas, hypotheses, and experimental designs for addressing the related scientific issues. **TRL 2 Decision Criterion:** Hypothesis(es) is generated. Research plans and/or protocols are developed, peer reviewed, and approved.	Intense intellectual focus on the problem, with generation of scientific "paper studies" that review and generate research ideas, hypotheses, and experimental designs for addressing the related scientific issues. **TRL 2 Decision Criterion:** Hypothesis(es) is generated. Research plans and/or protocols are developed, peer reviewed, and approved.	Intense intellectual focus on the problem, with generation of scientific "paper studies" that review and generate research ideas, hypotheses, and experimental designs for addressing the related scientific issues. **TRL 2 Decision Criterion:** Hypothesis(es) is generated. Research plans and/or protocols are developed, peer reviewed, and approved.	HW/SW system invention begins. Overall system concepts are documented by flowcharting or other system-descriptive techniques. **TRL 1 Decision Criterion:** Identification of the potential medical solution to mission need. Medical Informatics data and knowledge representation issues are defined.
	Supporting Information	**Supporting Information**	**Supporting Information**	
	Focused literature reviews conducted and scientific discussions held to generate research plans and studies that identify potential targets of opportunity for therapeutic intervention and to facilitate strategic planning. Supporting analyses provide scientific information and data for developing research proposals for filling in data gaps and identifying candidate concepts and/or therapeutic drugs. Documented by peer-reviewed, approved protocol(s) or research plan(s).	Focused literature reviews conducted and scientific discussions held to generate research plans and studies that identify potential targets of opportunity for therapeutic intervention and to facilitate strategic planning. Supporting analyses provide scientific information and data for developing research proposals for filling in data gaps and identifying candidate concepts and/or therapeutic drugs. Documented by peer-reviewed, approved protocol(s) or research plan(s).	Focused literature reviews conducted and scientific discussions held to generate research plans and studies that identify potential targets of opportunity for therapeutic intervention and to facilitate strategic planning. Supporting analyses provide scientific information and data for developing research proposals for filling in data gaps and identifying candidate concepts and/or devices. Documented by peer-reviewed, approved protocol(s) or research plan(s).	

Table I-1. Proposed TRLs for Medical (RDT&E) (Continued)

TRL 3	**NASA/*Interim Guidebook* TRL Definition:** Analytical and experimental critical function and/or characteristic proof-of-concept			
NASA/ *Interim Guidebook* TRL Description	***USAMRMC Equivalent TRL Descriptions***			
	Pharmaceutical (Drugs) TRL Description[N1, N2]	**Pharmaceutical (Biologics, Vaccines) TRL Description[N1, N2]**	**Medical Devices TRL Description [N3, N4]**	**Medical IM/IT & Medical Informatics**
Active research and development is initiated. This includes analytical studies and laboratory studies to physically validate analytical predictions of separate elements of the technology. Examples include components that are not yet integrated or representative.	Basic research, data collection, and analysis begin in order to test hypothesis, explore alternative concepts, and identify and evaluate technologies supporting drug development. Initial synthesis of countermeasure candidate(s) and identification of their sites and mechanisms of action. Initial characterization of candidates in preclinical studies. **TRL 3 Decision Criterion:** Initial proof-of-concept for candidate drug constructs is demonstrated in a limited number of *in vitro* and *in vivo* research models.	Basic research, data collection, and analysis begin in order to test hypothesis, explore alternative concepts, and identify and evaluate critical technologies and components supporting candidate biologic/vaccine constructs research and eventual development of a candidate countermeasure. Agent challenge studies are conducted to support models based on presumed battlefield conditions. Research-scale process initiation and evaluation conducted, as are studies to identify site(s) and mechanism(s) of action, potential correlates of protection for vaccines, and initial physical/chemical characterization of constructs. **TRL 3 Decision Criterion:** Initial proof-of-concept for biologic/vaccine constructs is demonstrated in a limited number of *in vitro* and *in vivo* research models.	Basic research, data collection, and analysis begin in order to test hypothesis, explore alternative concepts, and identify and evaluate component technologies. Initial tests of design concept, and evaluation of candidate(s). Study endpoints defined. Animal models (if any) are proposed. Design verification, critical component specifications, and tests (if a system component, or necessary for device T&E) developed. **TRL 3 Decision Criterion:** Initial proof-of-concept for device candidates is demonstrated in a limited number of laboratory models (may include animal studies).	Separate elements of HW/SW system components are investigated and developed but not yet integrated or representative. **TRL 3 Decision Criterion:** Medical Informatics data and knowledge representation schema are modeled.
	Supporting Information	**Supporting Information**	**Supporting Information**	
	Documentation of the results of laboratory studies demonstrates preliminary proof-of-concept in *in vitro* and animal studies.	Documentation of the results of laboratory studies demonstrates preliminary proof-of-concept with candidate biologic/vaccine constructs in *in vitro* and animal studies.	Documentation of the results of laboratory studies demonstrates preliminary proof-of-concept in laboratory models.	

Table I-1. Proposed TRLs for Medical (RDT&E) (Continued)

TRL 4 NASA/*Interim Guidebook* TRL Definition: Component and/or breadboard validation in laboratory environment				
NASA/ *Interim Guidebook* TRL Description	***USAMRMC Equivalent TRL Descriptions***			
	Pharmaceutical (Drugs) TRL Description[N1, N2]	**Pharmaceutical (Biologics, Vaccines) TRL Description**[N1, N2]	**Medical Devices TRL Description** [N3, N4]	**Medical IM/IT & Medical Informatics**
Basic technological components are integrated to establish that they will work together. This is relatively "low fidelity" compared to the eventual system. Examples include integration of "ad hoc" hardware in the laboratory.	Non-GLP laboratory research to refine hypothesis and identify relevant parametric data required for technological assessment in a rigorous (worst case) experimental design. Exploratory study of candidate drugs [e.g., formulation, route(s) of administration, method of synthesis, physical/ chemical properties, metabolic fate and excretion or elimination, and dose ranging]. Candidate drugs are evaluated in animal model(s) to identify and assess potential safety and toxicity problems, adverse events, and side effects. Assays to be used during nonclinical and clinical studies in evaluating candidate drugs are identified. **TRL 4 Decision: Criterion:** Proof-of-concept and safety of candidate drug formulation(s) demonstrated in defined laboratory/animal model(s).	Non-GLP laboratory to refine hypothesis and identify relevant parametric data required for technological assessment in a rigorous (worst case) experimental design. Exploratory study of critical technologies for effective integration into candidate biologic/vaccine constructs, for example, environmental milieu (pH, adjuvant, stabilizers and preservatives, buffers, etc.), route(s)/methods of administration, proposed production/purification methods, further physical/chemical characterization, metabolic fate and excretion or elimination, dose ranging, and agent challenge studies for protection. Candidate biologic/vaccine constructs are evaluated in animal model(s) to identify and assess safety and toxicity, biological effects, adverse effects, and side effects. Assays, surrogate markers, and endpoints to be used during nonclinical and clinical studies to evaluate and characterize candidate biologic/vaccine constructs are identified. **TRL 4 Decision Criterion:** Proof-of-concept and safety of candidate biologic/vaccine constructs demonstrated in defined laboratory/animal model(s).	Non-GLP laboratory research to refine hypothesis and identify relevant parametric data required for technological assessment in a rigorous (worst case) experimental design. Exploratory study of candidate device(s)/systems (e.g., initial specification of device, system, and subsystems). Candidate devices/systems are evaluated in laboratory and/or animal models to identify and assess potential safety problems, adverse events, and side effects. Procedures and methods to be used during nonclinical and clinical studies in evaluating candidate devices/systems are identified. The design history file, design review, and, when required, a master device record, are initiated to support either a 510(k) or PMA. **TRL 4 Decision Criterion:** Proof-of-concept and safety of candidate devices/systems demonstrated in defined laboratory/animal models.	Prototype produced. HW/SW System components are integrated to establish that the pieces will work together. This is relatively "low fidelity" compared to the eventual system. **TRL 4 Decision Criterion:** Medical Informatics data and knowledge representation models are instantiated with representative data or knowledge from applicable domain.
	Supporting Information	**Supporting Information**	**Supporting Information**	
	Documented proof-of-concept and safety of candidate drug formulations demonstrated by results of formulation studies, laboratory tests, pharmocokinetic studies, and selection of laboratory/ animal models.	Documented proof-of-concept and safety of candidate biologics/vaccines demonstrated by results of proposed production/purification methods, laboratory tests, pharmocokinetic studies, and selection of laboratory/animal models.	Reviewers confirm proof-of-concept and safety of candidate devices/systems from laboratory test results, laboratory/animal models, and documentation of the initial design history file, design review, and, when required, a master device record. The documented initial design history file, design review, and, when required, a master device record support either a 510(k) or PMA.	

Table I-1. Proposed TRLs for Medical (RDT&E) (Continued)

TRL 5 **NASA/*Interim Guidebook* TRL Definition:** Component and/or breadboard validation in a relevant environment				
NASA/ *Interim Guidebook* TRL Description	***USAMRMC Equivalent TRL Descriptions***			
	Pharmaceutical (Drugs) TRL Description[N1, N2]	**Pharmaceutical (Biologics, Vaccines) TRL Description[N1, N2]**	**Medical Devices TRL Description[N3, N4]**	**Medical IM/IT & Medical Informatics**
Fidelity of breadboard technology increases significantly. The basic technological components are integrated with reasonably realistic supporting elements so they can be tested in a simulated environment. Examples include "high-fidelity" laboratory integration of components.	Intense period of nonclinical and preclinical research studies involving parametric data collection and analysis in well-defined systems, with pilot lots of candidate pharmaceuticals produced and further development of selected candidate(s). Results of research with pilot lots provide basis for a manufacturing process amenable to cGMP-compliant pilot lot production. Conduct GLP safety and toxicity studies in animal model systems. Identify endpoints of clinical efficacy or its surrogate. Conduct studies to evaluate the pharmacokinetics and pharmacodynamics of candidate drugs. Stability studies initiated. **TRL 5 Decision Criterion:** A decision point is reached at which it is determined that sufficient data on the candidate drug exist in the draft technical data package to justify proceeding with preparation of an IND application.	Intense period of nonclinical and preclinical research studies involving parametric data collection and analysis in well-defined systems with pilot lots of candidate biologics/vaccines produced and further development of selected candidates. Research results support proposing a potency assay, proposing a manufacturing process amenable to cGMP-compliant pilot lot production, identifying and demonstrating proof-of-concept for a surrogate efficacy marker in an animal model(s) applicable to predicting protective immunity in humans, and demonstrating preliminary safety and efficacy against an aerosol challenge in a relevant animal model. Conduct GLP safety and toxicity studies in animal model systems. Identify endpoints of clinical efficacy or its surrogate in animal models that may be applicable to predicting protective immunity in humans. Conduct studies to evaluate immunogenicity, as well as pharmacokinetics and pharmacodynamics when appropriate. Stability studies initiated. **TRL 5 Decision Criterion:** A decision point is reached at which it is determined that sufficient data on the candidate biologic/vaccine exist in the draft technical data package to justify proceeding with preparation of an IND application.	Further development of selected candidate(s). Devices compared to existing modalities and indications for use and equivalency demonstrated in model systems. Examples include devices tested through simulation, in tissue or organ models, or animal models if required. All component suppliers/vendors are identified and qualified; vendors for critical components audited for cGMP/QSR compliance. Component tests, component drawings, design history file, design review, and any master device record verified. Product Development Plan drafted. Pre-IDE meeting held with CDRH for proposed Class III devices, and the IDE is prepared and submitted to CDRH. For a 510(k), determine substantially equivalent devices and their classification, validate functioning model, ensure initial testing is complete, and validate data and readiness for cGMP inspection. **TRL 5 Decision Criterion:** IDE review by CDRH results in determination that the investigation may begin. For a 510(k), preliminary findings suggest the device will be substantially equivalent to a predicate device.	First technical test of prototype. HW/SW system components are integrated, and realistic supporting elements are employed so that the system can be tested in a simulated environment. Actual interfaces to supporting systems are specified and development begins. **TRL 5 Decision Criterion:** Medical Informatics data and knowledge representation models are implemented as data and/or knowledge management systems and tested in a laboratory environment.

Table I-1. Proposed TRLs for Medical (RDT&E) (Continued)

TRL 5 **NASA/*Interim Guidebook* TRL Definition:** Component and/or breadboard validation in a relevant environment (Continued)

Pharmaceutical (Drugs) TRL Description[N1, N2]	Pharmaceutical (Biologics, Vaccines) TRL Description[N1, N2]	Medical Devices TRL Description[N3, N4]
Supporting Information	**Supporting Information**	**Supporting Information**
Reviewers confirm adequacy of information and data on candidate drug in draft technical data package to support preparation of IND application. Documentation in the draft technical data package contains data from animal pharmacology and toxicology studies, proposed manufacturing information, and clinical protocols for Phase 1 clinical testing.	Reviewers confirm adequacy of information and data on candidate biologic/vaccine constructs in draft technical data package to support preparation of an IND application. Documentation in the draft technical data package contains data from animal pharmacology and toxicology studies, proposed manufacturing information, and clinical protocols suitable for Phase 1 clinical testing.	For investigation of a Class III device to begin in humans: The FDA's and sponsor's summary minutes of pre-IDE meeting document agreements and general adequacy of information and data to support preparation and submission of IDE application. FDA letter acknowledging receipt of IDE by CDRH. The investigational plan (clinical trials) may begin after 30 days (barring a clinical hold from the FDA) or sooner if CDRH approves the IDE within 30 days. In the latter case, CDRH will provide written notification. The submitted IDE includes information regarding sponsor, intended use of device, rationale for use of device, investigational plan, instructions for use of device, labeling, and informed consent. For a 510(k) device, reviewers confirm preliminary claim that the medical device appears substantially equivalent to a predicate device, the proposed classification is consistent with 21CFR860, there is a functioning model, and testing results support substantial equivalency.

Table I-1. Proposed TRLs for Medical (RDT&E) (Continued)

TRL 6 NASA/*Interim Guidebook* TRL Definition: System/subsystem model or prototype demonstration in a relevant environment

NASA/ *Interim Guidebook* TRL Description	USAMRMC Equivalent TRL Descriptions: Pharmaceutical (Drugs) TRL Description[N1, N2]	Pharmaceutical (Biologics, Vaccines) TRL Description[N1, N2]	Medical Devices TRL Description[N3, N4]	Medical IM/IT & Medical Informatics
Representative model or prototype system, which is well beyond that of TRL 5, is tested in a relevant environment. Represents a major step up in a technology's demonstrated readiness. Examples include testing a prototype in a high-fidelity laboratory environment or in [a] simulated operational environment.	Pre-IND meeting (Type B) held with CDER. IND application prepared and submitted. Phase 1 clinical trials are conducted to demonstrate safety of candidate in a small number of humans under carefully controlled and intensely monitored clinical conditions. Evaluation of pharmacokinetic and pharmacodynamic data to support the design of well-controlled, scientifically valid Phase 2 studies. Production technology demonstrated through production-scale cGMP plant qualification. **TRL 6 Decision Criterion:** Data from Phase 1 trials meet clinical safety requirements and support proceeding to Phase 2 clinical studies.	Pre-IND meeting (Type B) held with CBER. IND application prepared and submitted. Phase 1 clinical trials are conducted to demonstrate safety of candidates in a small number of subjects under carefully controlled and intensely monitored clinical conditions. Evaluation of immunogenicity and/or pharmacokinetics and pharmacodynamics data to support design of Phase 2 clinical trials. Surrogate efficacy models are validated. **TRL 6 Decision Criterion:** Data from Phase 1 clinical trials meet clinical safety requirements and support proceeding to Phase 2 clinical trials.	Clinical trials conducted to demonstrate safety of candidate Class III medical device in a small number of humans under carefully controlled and intensely monitored clinical conditions. Component tests, component drawings, design history file, design review, and any master device record updated and verified. Production technology demonstrated through production-scale cGMP plant qualification. For 510(k), component tests, component drawings, design history file, design review, and any master device record updated and verified. Manufacturing facility ready for cGMP inspection. **TRL 6 Decision Criterion:** Data from the initial clinical investigation demonstrate that the Class III device meets safety requirements and support proceeding to clinical safety and effectiveness trials. For a 510(k), information and data demonstrate substantial equivalency to predicate device and support production of the final prototype and final testing in a military operational environment.	Advanced technical testing of prototype HW/SW system, to include interfaces to actual supporting systems, is tested in a relevant or simulated operational environment. Out-product is final prototype. **TRL 6 Decision Criterion:** Medical Informatics data and knowledge management systems are tested with target applications in a laboratory environment. Configuration management developed.
	Supporting Information	**Supporting Information**	**Supporting Information**	
	For Phase 1 Clinical Trials to begin: The FDA's and sponsor's summary minutes of pre-IND meeting document agreements and general adequacy of information and data to support submission of IND application. Review of the submitted IND application does not result in a FDA decision to put a clinical hold on Phase 1 clinical trials with the candidate drug. For entry into Phase 2 Clinical Trials: Results from Phase 1 clinical studies demonstrate safety of candidate drug. An updated IND application, amended with a new clinical protocol to support Phase 2 clinical trials, or a surrogate test plan, and submitted to the FDA documents the achievement of this criterion.	For Phase 1 Clinical Trials to begin: The FDA's and sponsor's summary minutes of pre-IND meeting document agreements and general adequacy of information and data to support submission of an IND application. Review of the submitted IND does not result in a FDA decision to put a clinical hold on Phase 1 clinical trials with the candidate biologic/vaccine. For entry into Phase 2 Clinical Trials: Results from Phase 1 clinical studies demonstrate safety of candidate biologic/vaccine. An updated IND, amended with a new clinical protocol to support Phase 2 clinical trials, or surrogate test plan, and submitted to the FDA documents achieving this criterion.	Documentation from clinical study results shows the candidate device is safe. Changes to the investigational plan that require FDA approval (21CFR812.35) are submitted as a supplemental IDE application to the FDA. For a 510(k), reviewers confirm adequacy of documented component tests, component drawings, design history file, design review, and any master device record to support claim of substantial equivalency and readiness for final testing in a military operational environment.	

Table I-1. Proposed TRLs for Medical (RDT&E) (Continued)

TRL 7 — NASA/*Interim Guidebook* TRL Definition: System prototype demonstration in an operational environment

NASA/ *Interim Guidebook* TRL Description	USAMRMC Equivalent TRL Descriptions: Pharmaceutical (Drugs) TRL Description[N1, N2]	Pharmaceutical (Biologics, Vaccines) TRL Description[N1, N2]	Medical Devices TRL Description[N3, N4]	Medical IM/IT & Medical Informatics
Prototype near, or at, planned operational system. Represents a major step up from TRL 6, requiring demonstration of an actual system prototype in an operational environment such as an aircraft, vehicle, or space. Examples include testing the prototype in a test bed aircraft.	Phase 2 clinical trials conducted to demonstrate initial efficacy and capture further safety and toxicity data. Product activity (e.g., preliminary evidence of efficacy) determined. Product final dose, dose range, schedule, and route of administration established from clinical pharmacokinetic and pharmacodynamic data. Phase 2 clinical trials completed. Data are collected, presented, and discussed with CDER at pre-Phase 3 meeting (Type B) in support of continued drug development. Clinical endpoints and/or surrogate efficacy markers and test plans agreed to by CDER. **TRL 7 Decision Criterion:** Phase 3 clinical study plan or surrogate test plan has been approved.	Phase 2 safety and immunogenicity trials conducted. Product immunogenicity and biological activity (e.g., preliminary evidence of efficacy) determined. Product final dose, dose range, schedule, and route of administration established from vaccine immunogenicity and biologic activity and, when necessary, from clinical pharmacokinetics and pharmacodynamics data. Phase 2 clinical trials completed. Data are collected, presented, and discussed with CBER at pre-Phase 3 (or surrogate efficacy) meeting (Type B) in support of continued development of the biologics/ vaccines. Clinical endpoints and/or surrogate efficacy markers and test plans agreed to by CBER. **TRL 7 Decision Criterion:** Phase 3 clinical study plan or surrogate test plan has been approved.	Clinical safety and effectiveness trials conducted with a fully integrated Class III medical device prototype in an operational environment. Continuation of closely controlled studies of effectiveness and determination of short-term adverse events and risks associated with the candidate product. Functional testing of candidate devices completed and confirmed, resulting in final down-selection of prototype device. Clinical safety and effectiveness trials completed. Final product design validated, and final prototype and/or initial commercial scale device are produced. Data collected, presented, and discussed with CDRH in support of continued device development. For a 510(k), final prototype and/or initial commercial-scale device are produced and tested in a military operational environment. **TRL 7 Decision Criterion:** Clinical endpoints and test plans agreed to by CDRH. For a 510(k), information and data demonstrate substantial equivalency to predicate device and use in a military operational environment and support preparation of 510(k).	Prototype HW/SW system is near or at planned operational system. Actual system prototype demonstrated in an operational environment with end-users (first cut user test). **TRL 7 Decision Criterion:** Medical Informatics data and knowledge management systems are operationally integrated and tested with target applications in an operational environment.
	Supporting Information	**Supporting Information**	**Supporting Information**	
	FDA's summary minutes of pre-Phase 3 meeting with sponsor discussing results of Phase 1 and Phase 2 trials, and protocols or test plans provide record of agreements and basis for sponsor to proceed with Phase 3 clinical study or surrogate test plan. An updated IND application, amended with a new clinical protocol to support Phase 3 clinical trials, or surrogate test plan, and submitted to the FDA documents the achievement of this criterion.	FDA's summary minutes of pre-Phase 3 meeting with sponsor discussing results of Phase 1 and Phase 2 trials, as well as clinical protocols or test plans, provide record of agreements and basis for sponsor to proceed with Phase 3 clinical study or surrogate test plan. An updated IND application, amended with a new clinical protocol to support Phase 3 clinical trials, or surrogate test plan, and submitted to the FDA documents achieving this criterion.	The FDA's and sponsor's summary minutes of their meeting documents any agreements reached regarding continued development of the Class III medical device. PMA shell modules (e.g., sections of PMA) submitted to CDRH by sponsor if such submissions were previously approved by CDRH. For a 510(k), documented results of testing in an operational environment support safety, effectiveness, and use of device in a military operational environment.	

Table I-1. Proposed TRLs for Medical (RDT&E) (Continued)

TRL 8 NASA/*Interim Guidebook* TRL Definition: Actual system completed and "flight qualified" through test and demonstration

NASA/ *Interim Guidebook* TRL Description	*USAMRMC Equivalent TRL Descriptions*			
	Pharmaceutical (Drugs) TRL Description[N1, N2]	**Pharmaceutical (Biologics, Vaccines) TRL Description[N1, N2]**	**Medical Devices TRL Description [N3, N4]**	**Medical IM/IT & Medical Informatics**
Technology has been proven to work in its final form and under expected conditions. In almost all cases, this TRL represents the end of true system development. Examples include developmental test and evaluation of the system in its intended weapon system to determine if it meets design specifications.	Implementation of expanded Phase 3 clinical trials or surrogate tests to gather information relative to the safety and effectiveness of the candidate drug. Trials are conducted to evaluate the overall risk-benefit of administering the candidate product and to provide an adequate basis for drug labeling. Process validation completed and followed by lot consistency/reproducibility studies. Pre-NDA meeting (Type B) held with CDER. NDA prepared and submitted to CDER. Facility PAI completed. **TRL 8 Decision Criterion:** Approval of the NDA for drug by CDER.	Implementation of expanded Phase 3 clinical trials or surrogate tests to gather information relative to the safety and effectiveness of the candidate biologic/vaccine. Trials are conducted to evaluate the overall risk-benefit of administering the candidate product and to provide an adequate basis for product labeling. Process validation completed and followed by lot consistency/reproducibility studies. Pre-BLA meeting (Type B) held with CBER. BLA prepared and submitted to CBER. Facility PAI completed. **TRL 8 Decision Criterion:** Approval of the BLA for biologics/vaccines by CBER.	Implementation of clinical trials to gather information relative to the safety and effectiveness of the device. Trials are conducted to evaluate the overall risk-benefit of using the device and to provide an adequate basis for product labeling. Confirmation of QSR compliance, the design history file, design review, and any master device record, are completed and validated, and device production followed through lot consistency and/or reproducibility studies. Pre-PMA meeting held with CDRH. PMA prepared and submitted to CDRH. Facility PAI (cGMP/QSR/QSIT) completed. For 510(k), prepare and submit application. **TRL 8 Decision Criterion:** Approval of the PMA [or, as applicable, 510(k)] for device by CDRH.	Technical testing of final product. HW/SW system has been proven to work in its final form and under expected conditions. **TRL 8 Decision Criterion:** Developmental test and evaluation of the HW/SW system in its intended environment demonstrate it meets design specifications. Fully integrated and operational medical informatics data and knowledge management systems are validated in several operational environments.
	Supporting Information	**Supporting Information**	**Supporting Information**	
	FDA issuance of an Approval letter after their review of the NDA submitted by the sponsor for the drug documents this criterion.	FDA issuance of an Approval letter after their review of the BLA application submitted by the sponsor for the pharmaceutical (biologic/vaccine) documents this criterion.	FDA issuance of an Approval Order after their review of PMA application submitted by the sponsor for the Class III medical device. The submitted PMA includes general information, summary of safety and effectiveness data, device description and manufacturing information, summaries of nonclinical and clinical studies, labeling, and instruction manual. For a 510(k), FDA issuance of a Marketing Clearance letter (also referred to as a "substantially equivalent letter") after their review of 510(k) application submitted by the sponsor for the medical device.	

Table I-1. Proposed TRLs for Medical (RDT&E) (Continued)

TRL 9	**NASA/*Interim Guidebook* TRL Definition:** Actual system "flight proven" through successful mission operations			
NASA/ *Interim Guidebook* TRL Description	***USAMRMC Equivalent TRL Descriptions***			
	Pharmaceutical (Drugs) TRL Description[N1, N2]	**Pharmaceutical (Biologics, Vaccines) TRL Description[N1, N2]**	**Medical Devices TRL Description [N3, N4]**	**Medical IM/IT & Medical Informatics**
Actual application of the technology in its final form and under mission conditions, such as those encountered in operational test and evaluation. Examples include using the system under operational mission conditions.	The pharmaceutical (i.e., drug, biologic, or vaccine) or medical device may be distributed/ marketed. Postmarketing studies (nonclinical or clinical) may be required and are designed after agreement with the FDA. Postmarketing surveillance. **TRL 9 Decision Criterion:** None. Continue surveillance.	The pharmaceutical (i.e., drug, biologic, or vaccine) or medical device may be distributed/ marketed. Postmarketing studies (nonclinical or clinical) may be required and are designed after agreement with the FDA. Postmarketing surveillance. **TRL 9 Decision Criterion:** None. Continue surveillance.	The pharmaceutical (i.e., drug, biologic, or vaccine) or medical device may be distributed/ marketed. Postmarketing studies (nonclinical or clinical) may be required and are designed after agreement with the FDA. Postmarketing surveillance. **TRL 9 Decision Criterion:** None. Continue surveillance.	Operational testing of the product. HW/SW system is in its final form and under mission conditions, such as those encountered in operational test and evaluation. Medical Informatics knowledge maintenance and verification of data integrity are ongoing. Military requirements met for transportation, handling, storage, etc. **TRL 9 Decision Criterion:** Product successfully used during military mission as component of IOT&E phase. Logistical demonstration successfully conducted.
	Supporting Information	**Supporting Information**	**Supporting Information**	
	FDA transmits any requirement for postmarketing studies. Begin postapproval reporting requirements. Maintain cGMP compliance.	FDA transmits requirements for any postmarketing studies. Begin postapproval reporting requirements. Maintain cGMP compliance.	FDA transmits requirements for any postmarketing studies. Begin postapproval reporting requirements. Maintain cGMP compliance.	

Note 1 for Table I-1: *These guidelines are not considered absolutes, and characterization of activities associated with TRLs can and does vary at times. For example, experience to date in applying the guidelines for biomedical TRLs indicates considerable variation in the timing, activities, and programmatic events associated with TRLs 5 and 6 for pharmaceuticals. Hence, the S&T and acquisition PMs work together in exercising discretion in the selection, progression, and timing of specific activities to be accomplished in the attainment of TRL 5. Such flexibility and tailoring are needed to align the TRL decision criteria appropriately with the maturation and risk characteristics of a particular technology, including consideration of the associated investment strategy and transition procedures that may vary among PMs.*

Note 2 for Table I-1: *Descriptions and decision criteria are from Biomedical Technology Readiness Levels (TRLs), prepared for the Commander, U.S. Army Medical Research and Materiel Command. under Contract number DAMD17-98-D-0022, Science Applications International Corporation, 3 June 2003.*

Note 3 for Table I-1: *These guidelines are not considered absolutes, and characterization of activities associated with TRLs can and does vary at times. For example, experience to date with application of the guidelines for biomedical TRLs indicates considerable variation in the timing, activities, and programmatic events associated with medical devices that follow a 510(k) vis-à-vis PMA path. Hence, the S&T and acquisition PMs work together in exercising discretion in the selection, progression, and timing of specific activities to be accomplished in the attainment of particular TRLs. Such flexibility and tailoring are needed to align the TRL decision criteria appropriately with the maturation and risk characteristics of a particular technology, including consideration of the associated investment strategy and transition procedures that may vary among PMs.*

Note 4 for Table I-1: *Descriptions and decision criteria are from Biomedical Technology Readiness Levels (TRLs), prepared for the Commander, U.S. Army Medical Research and Materiel Command. under Contract number DAMD17-98-D-0022, Science Applications International Corporation, 3 June 2003. Definitions pertain predominately to Class II and Class III devices (see 21CFR860.3 or Glossary of this appendix for device class definitions) that are subject to approval via the PMA process. Devices that are subject to approval via the 510(k) process (Market clearance; generally limited to certain Class I and Class II devices) may not require all of the studies described and only require an Investigational Device Exemption (IDE) on if human studies are necessary.*

B. THE FDA REGULATORY PROCESS

The FDA regulates products to protect the public health by ensuring that human pharmaceuticals (drugs and biologics/vaccines) are safe and effective and that there is reasonable assurance of the safety and effectiveness of medical devices intended for human use in the United States. Three FDA centers are charged with this mission:

1. **The FDA Center for Drug Evaluation and Research (CDER).** CDER regulates drugs and some biologic products (antibodies, cytokines, growth factors, enzymes, and proteins extracted from animals or microorganisms).

2. **The FDA Center for Biologics Evaluation and Research (CBER).** CBER regulates vaccines, blood and plasma products, viral-vectored gene therapy, products composed of human or animal cells, antitoxins, and select *in vitro* diagnostics. CBER also holds regulatory authority over Human Immunodeficiency Virus (HIV) test kits and medical devices involved in collecting, processing, testing, manufacturing, and administering blood products.

3. **The FDA Center for Devices and Radiological Health (CDRH).** CDRH is responsible for regulating manufactured, repackaged, relabeled, and/or imported medical devices that are sold in the United States (except those devices regulated by CBER).

1. Pharmaceuticals

Drugs and biologics/vaccines follow parallel developmental regulatory pathways (see Table I-1). During preclinical development, the sponsor evaluates the toxicology and pharmacology of the new drug or biologic through *in vitro* and animal testing. Preclinical test results and any available past human experiences of the drug or biologic are incorporated in an Investigational New Drug (IND) application and submitted to the FDA for review. If no safety issues are found, human clinical testing of the new drug or biologic can be initiated after 30 days. Clinical testing proceeds in three successive phases, starting with a small group of human subjects (Phase 1) and progressing to a larger population of human subjects (Phase 3). Only by qualified investigators, selected by the sponsor, and in accordance with Good Clinical Practice (GCP) [21CFR312.53 and 21CFR312.62 *Federal Register* 25692], conduct clinical trials. The safety and effectiveness results of clinical testing comprise the most important factor in the approval or disapproval of the new drug or biologic. All active INDs require submission of an annual IND report to the FDA. The results of the human clinical tests and all chemistry and manufacturing information are submitted either in a New Drug Application (NDA) for drug products or a Biologics License Application (BLA) for biologic products. The appropriate FDA center reviews the NDA or BLA, and, upon approval, the drug or biologic product can be entered into interstate commerce or marketed in the United States. FDA approval is for the specific indication(s) identified in the marketing application. Additional or modified medical indications require the submission of an amendment or a new marketing application. A new marketing application may require additional human clinical data acquired

through IND regulations. With some new drugs or biologics/vaccines, the FDA may require additional reporting requirements after approval, termed Phase 4 or postmarketing surveillance. Manufacturers are required to track and report the number and severity of adverse events attributable to each product for a specified time period. Severe adverse events detected during postapproval can lead to a product recall or mandatory withdrawal from the market. All drugs and biologics/vaccines must comply with current Good Manufacturing Practice (cGMP) and labeling regulations.

With certain drug or biologic products, human clinical studies are not ethical or feasible because the studies would involve administering a potentially lethal or permanently disabling toxic substance or organism to healthy human volunteers. In 2002, the FDA addressed this issue with new regulations that allow for the approval of new drug and biologic products based on evidence of effectiveness in animals [21CFR314 and 21CFR601]. In February 2003 under the new federal regulations, DoD was able to gain approval of pyridostigmine bromide for prophylaxis against the lethal effects of the soman nerve agent.

2. Medical Devices

The FDA CDRH regulates most medical devices, and they have classified each device in the Code of Federal Regulations (CFR). Classification of devices into one of three classes is based on the level of regulatory control that is necessary to ensure the safety and effectiveness of a medical device, with Class I and Class III devices being the least and most regulated, respectively. The sponsor normally proposes the classification level of a device using 21CFR860 as a guide. Most importantly, the classification of the device will identify, unless exempt (e.g., most of the Class I devices), the marketing process [either premarket notification (510(k)) or premarket approval (PMA)] that the manufacturer must complete to obtain FDA clearance/approval for marketing. All classified medical devices are subject to cGMPs and labeling requirements. An approved 510(k) or PMA allow an applicant to market a particular device for its intended purpose.

The FDA approves most medical devices for marketing in the United States through a premarket notification (510(k)). The applicant must show that the new device is substantially equivalent to one or more predicate devices legally marketed in the United States. A description of all tests conducted and the results obtained must be provided in sufficient detail to allow the FDA to determine substantial equivalence. If the medical device is found to be substantially equivalent, the FDA will send the manufacturer a “substantially equivalent letter” to clear the device for marketing. If the FDA finds the device not to be substantially equivalent, the FDA sends the manufacturer a “not substantially equivalent letter,” and the device cannot be marketed. At this point, the manufacturer can submit another 510(k) with new and/or additional information to support substantial equivalence, or the manufacturer may be required to submit a PMA.

To allow a Class III medical device (devices are those that support or sustain human life or present a potential risk of serious illness or injury) into interstate commerce or marketing, a

PMA is required. A PMA is the most stringent regulatory submission for medical devices. Class III devices follow somewhat different development and regulatory paths compared with those for drugs and biologics/vaccines (see Table I-1). For example, if human clinical information is required to establish safety and efficacy, the regulatory application used to allow human clinical trials is called an Investigational Device Exemption (IDE). Approval of an IDE allows the initiation of human clinical trials of an investigational device. Qualified principal investigators (PIs), selected by the sponsor in accordance with 21CFR812.43, conduct clinical trials. All active IDEs require submission of an annual report to the FDA. Safety and efficacy information acquired during the IDE process is used to support the submission of a PMA, and the FDA must approve the PMA before the device can be marketed. As with drugs and biologics/vaccines, the FDA may mandate a period of postmarketing surveillance during which device-related adverse events must be tracked and reported.

C. POCs

FDA Center for Devices and Radiological Health (CDRH)
Web site: http://www.fda.gov/cdrh/
Questions related to DoD or military:
Ronald Parr: rpp@cdrh.fda.gov, 301-443-6597, ext. 109
Thomas Cardamone: tec@cdrh.fda.gov, 301-443-0806, ext. 115
Questions can also be addressed to:
Division of Small Manufacturers, International and Consumer Assistance (DSMICA)
dsmica@cdrh.fda.gov

FDA Center for Drug Evaluation and Research (CDER)
Procedures, forms, policies, guidance documents, and regulations related to the drug approval process may be accessed from the Web site:
http://www.fda.gov/cder/regulatory/applications/default.htm
Questions related to DoD or military:
Division of Counter-Terrorism (HFD-970)
CDER
Voice: 301-827-7709
Fax: 301-827-7722
Questions can also be addressed to:
CDER Division of Drug Information
301-827-4573
druginfo@cder.fda.gov

FDA Center for Biologics Evaluation and Research (CBER)
Web site: http://www.fda.gov/cber/index.html
Questions may be addressed to:

CBER Manufacturers Assistance and Technical Training Branch
800-835-4709 or 301-827-1800
MATT@cber.fda.gov

D. ADDITIONAL INFORMATION

Federal Food, Drug, and Cosmetic Act (FD&C Act)

United States Code, Title 21 – Food and Drugs (21USC)
Chapter 9: Federal Food, Drug, and Cosmetic Act
http://www.access.gpo.gov/uscode/title21/chapter9_.html

FDA Regulations

Code of Federal Regulations (CFR): Title 21 – Food and Drugs (21CFR)
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm or
http://www.access.gpo.gov/nara/cfr/index.html

Drug Approval

The CDER Handbook: http://www.fda.gov/cder/handbook/
CDERLearn: http://www.fda.gov/cder/learn/CDERLearn/default.htm

Medical Device Approval

Device Advice: http://www.fda.gov/cdrh/devadvice/index.html

Laws Enforced by the FDA:

http://www.fda.gov/opacom/laws/lawtoc.htm

Protection of Human Subjects:

32CFR219- *Protection of Human Subjects* (also referred to as the "Common Rule")
(http://www.access.gpo.gov/nara/cfr/waisidx_02/32cfr219_02.html)

DoDD 3216.2 (March 25, 2002) *Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research*
http://www.dtic.mil/whs/directives/corres/pdf/d32162_032502/d32162p.pdf

GLOSSARY[15]

Approval Letter: A written communication to an applicant from the Food and Drug Administration (FDA) approving an application or an abbreviated application to market a drug. [21CFR314.3]

Approval Order: A written communication to an applicant from the FDA approving a Premarket Approval (PMA) for a Medical Devices application. [21CFR814.44]

Biologic or Biological Product: Any virus, therapeutic serum, toxin, antitoxin, or analogous product applicable to the prevention, treatment, or cure of diseases or injuries of man. [21CFR600.3]

Biologics License Application (BLA): An application to the FDA for approval to market a biological product. [21CFR601.12]

current Good Manufacturing Practices (cGMP): Regulations that cover the methods used in and the facilities and controls used for the design, manufacture, packaging, storage, and installation of devices. [21CFR820]

Class (Device): One of the three categories of regulatory control for medical devices. [21CFR860.3]

Class I Device: The class of devices for which general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. In the absence of sufficient information to make that determination, the device is not life supporting and does not present a potential unreasonable risk of illness or injury. [21CFR860.3]

Class II Device: The class of devices for which general controls alone are insufficient to provide reasonable assurance of its safety and effectiveness and for which there is sufficient information to establish special controls, including the promulgation of performance standards. For a device that is purported to be for use in supporting human life, the Commissioner (FDA) shall examine and identify the special controls, if any, that are necessary to provide adequate assurance of safety and effectiveness. [21CFR860.3]

Class III Device: The class of devices for which premarket approval is or will be required. A device is in Class III if insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of its safety and effectiveness, if the device is life supporting, or if the device presents a potential unreasonable risk of illness or injury. [21CFR860.3]

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15 Complete definitions and explanations of terms can be found in the source cited in brackets. CFR is an acronym for the Code of Federal Regulations.

Classification Name: The term used by the FDA and its classification panels to describe a device or class of devices for purposes of classifying devices under section 513 of the Federal Food, Drug, and Cosmetic (FD&C) Act. [21CFR807.3]. Approximately 1,700 different generic types of devices are grouped into 16 medical specialties. [21CFR862-892]

Clinical Hold: An FDA order to delay proposed clinical investigation or to suspend an ongoing investigation.

Clinical Investigation: Any experiment in which a drug that involves one or more human subjects is administered, dispensed to, or used. For this part, an experiment is any use of a drug except for the use of a marketed drug in the course of medical practice. [21CFR312.3]

Clinical Trial/Study: Any investigation in human subjects intended to discover or verify the clinical, pharmacological, and/or other pharmacodynamic effects of an investigational product(s), and/or identify any adverse reactions to an investigational product(s), and/or study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. The terms clinical trial and clinical study are synonymous. [62FR25692]

Cosmetic: (1) Articles intended to be rubbed, poured, sprinkled or sprayed on, introduced into or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering appearance and (2) articles intended for use as a component of any such article. This term shall not include soap.

Device Master Record (DMR): A compilation of records containing the procedures and specifications for a finished device. [21CFR820.3]

Drug or Drug Substance: An active ingredient that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or any function of the human body. [21CFR314.3]

Drug Product: A finished dosage form (e.g., tablet, capsule, or solution) that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients. [21CFR314.3]

FD&C Act: The Federal Food, Drug, and Cosmetic Act [21USC301-397]

FDA-Approved: FDA designation given to drugs, biologics, and medical devices that have approved marketing applications. Additional or modified medical indications for use require submission of an amendment or a new marketing application. A new marketing application may require additional human clinical data acquired through Investigational New Drug (IND) regulations.

General Controls: The baseline requirements of the FD&C Act that apply to all medical devices. In addition to prohibiting adulteration, misbranding, and banned devices, the general controls contain requirements for device manufacturers. These requirements include device listing, proper labeling, (manufacturing) establishment registration, and premarket notification [510(k)].

Good Clinical Practice (GCP): A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials. It provides assurance that the data and reported results are credible and accurate and that the rights, integrity, and confidentiality of trial subjects are protected. [62FR25692]

Good Laboratory Practice (GLP): Practices for conducting nonclinical laboratory studies that support or are intended to support applications for research or marketing permits for products regulated by the FDA. [21CFR58.1]

Investigational Device Exemption (IDE): Allows the investigational device to be used in a clinical study to collect safety and effectiveness data required to support a PMA application or a Premarket Notification [510(k)] submission to the FDA. [21CFR50, 56, 812]

Investigational New Drug (IND): A new drug or biological that is used in a clinical investigation. The term also includes a biological product that is used *in vitro* for diagnostic purposes. [21CFR312.3]

IND Application [21CFR312.3]: Allows a pharmaceutical (drug/biologic) to be used in a study under carefully controlled and intensely monitored conditions in order to collect safety and effectiveness data required to support a New Drug Application (NDA) or BLA.

Investigator: A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator (or PI). [62FR25692]

Label: Any display of written, printed, or graphic matter on the immediate container or package of, or affixed to any article.

Labeling: Any written, printed or graphic matter accompanying an article at any time while such article is in interstate commerce or held for sale after shipment in interstate commerce. This includes manuals, brochures, advertising, and so forth.

License: The terminology used for FDA's approval to market a biological pharmaceutical for a given set of indications (see also **FDA Approved**).

Life-Supporting or Life-Sustaining Device: A device that is essential to or that yields information that is essential to the restoration or continuation of a bodily function important to the continuation of human life. [21CFR860.3]

Medical Device: An instrument, apparatus, implement, machine, contrivance, implant, *in vitro* reagent, or other similar or related article, including any component, part, or accessory that is

- Recognized in the official National Formulary or U.S. Pharmacopoeia or any supplement to them
- Intended for use in diagnosing disease or other conditions or in curing, mitigating, treating, or preventing disease in man or other animals
- Intended to affect the structure or any function of the body of man or other animals and does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and is not dependent upon being metabolized for achievement of any of its primary intended purposes [Section 201(h) of the FD&C Act].

New Drug Application (NDA): An application to the FDA for approval to market a new drug. [21CFR314.50]

Preapproval Inspection (PAI): An FDA inspection of a facility to

- Verify the integrity (truthfulness, accuracy, and completeness) of data submitted in support of an application
- Evaluate the manufacturing controls for the preapproval batches upon which the application is based to be certain that the company can actually meet the commitments in the chemistry, manufacturing, and controls (CMC) section of the application
- Evaluate the capability of the manufacturer to comply with GMPs
- Collect samples for analysis.

Postmarketing Surveillance: Tracking and reporting the number and severity of adverse events attributable to each product. This may be a requirement for licensure for a defined period of time following licensure.

Premarket Approval for Medical Devices (PMA): Because of the level of risk associated with Class III devices, an applicant must receive FDA approval of its PMA application before marketing the device. PMA approval is based on a determination by FDA that the PMA contains sufficient valid scientific evidence to ensure that the device is safe and effective for its intended use(s). [21CFR814]

Premarket Notification 510(k): An application submitted to the FDA to demonstrate that a device is substantially equivalent [see 21USC513(I)(1)(A)] to a device that is legally in commercial distribution in the United States before May 28, 1976, or to a device that has been determined by FDA to be substantially equivalent. [21CFR807.81]

Quality System Inspection Technique (QSIT): An FDA inspection technique that focuses on the first four elements of the seven inspectional subsets of the Quality System Regulation (QSR).

Quality System Regulation (QSR): The 1996 rewrite of the device section of the cGMPs. [21CFR820]

Serious Adverse Event (SAE) or Serious Adverse Drug Reaction (ADR): Any untoward medical occurrence that at any dose

- Results in death
- Is life threatening
- Requires inpatient hospitalization or prolongation of existing hospitalization
- Results in persistent or significant disability/incapacity
- Causes a congenital anomaly/birth defect.

[See the International Conference on Harmonisation (ICH) guidance for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting]. [62FR25692]

Special Controls: Class II devices include any device for which reasonable assurance of safety and effectiveness can be obtained by applying "special controls." Special controls can include special labeling requirements, mandatory performance standards, patient registries, and postmarket surveillance.

Sponsor: An individual, company, institution, or organization that takes responsibility for the initiation, management, and/or financing of a clinical trial. [62FR25692]

Subject: A human who participates in an investigation, either as a recipient of the IND or as a control. [21CFR312.3]

Substantial Equivalence (SE): A device is substantially equivalent if, in comparison to a legally marketed device, it has the same intended use as a predicate and has the same technological characteristics as the predicate device. SE does not mean the devices are identical. [21CFR807.87]

Type B Meeting: Type B meetings are (1) pre-IND meetings (21CFR312.82), (2) certain end of Phase 1 meetings (21CFR312.82), (3) end of Phase 2/pre-Phase 3 meetings (21CFR312.47), and (4) pre-NDA/BLA meetings (21CFR312.47).

ACRONYMS AND ABBREVIATIONS FOR APPENDIX F

510(k)	Premarket Notification for Medical Devices
ADR	Adverse Drug Reaction
BLA	Biologics License Application
CBER	Center for Biologics Evaluation and Research
CDER	Center for Drug Evaluation and Research
CDRH	Center for Devices and Radiologic Health
CFR	Code of Federal Regulations
cGMP	Current Good Manufacturing Practices
CMC	chemistry, manufacturing, and controls
DMR	Device Master Record
DoD	Department of Defense
DSMICA	Division of Small Manufacturers, International and Consumer Assistance
FD&C	Federal Food, Drug, and Cosmetic
FDA	Food and Drug Administration
GAO	U.S. General Accounting Office
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
HFD	An FDA mailing address (e.g., HFD-970)
HIV	Human Immunodeficiency Virus
HW/SW	hardware/software
ICH	International Conference on Harmonisation
IDE	Investigational Device Exemption
IM/IT	Information Management/Information Technology
IND	Investigational New Drug Application
IOT&E	initial operational test and evaluation
MAIS	Major Automated Information System
MATT	Manufacturers Assistance and Technical Training
MDA	Milestone Decision Authority
MDAP	Major Defense Acquisition Program
NARA	National Archives and Records Administration
NASA	National Aeronautics and Space Administration
NDA	New Drug Application
OPA	Office of Premarket Approval
PAI	Preapproval Inspection
PI	principal investigator
PM	program manager
PMA	Premarket Approval
POC	point of contact
QSIT	Quality System Inspection Technique
QSR	Quality System Regulation
R&D	research and development

RDT&E	research, development, test and evaluation
S&T	science and technology
SAE	Serious Adverse Event
SE	Substantial Equivalence
T&E	test and evaluation
TRL	Technology Readiness Level
USC	United States Code
USAMRMC	United States Army Medical Research and Materiel Command

APPENDIX G
MANUFACTURING READINESS

APPENDIX G
MANUFACTURING READINESS

Matters of manufacturing readiness and producibility are as important to the successful development of a system as those of readiness and capabilities of the technologies intended for the system. Their importance has long been recognized in Department of Defense (DoD) acquisition and it is currently reflected in Department of Defense Directive (DoDD) 5000.1. Specifically, from DoDD 5000.1:

> E.1.14 Knowledge-Based Acquisition. PMs shall provide knowledge about key aspects of a system at key points in the acquisition process. PMs shall reduce technology risk, demonstrate technologies in a relevant environment, and identify technology alternatives, prior to program initiation. They shall reduce integration risk and demonstrate product design prior to the design readiness review. They shall reduce *manufacturing risk and demonstrate producibility* (emphasis added) prior to full-rate production.

In accordance with this policy, Department of Defense Instruction (DoDI 5000.2) specifies the requirements for assessing or demonstrating the manufacturing readiness of a system at various stages of its development.

Currently, standard methods and metrics similar to Technology Readiness Levels (TRLs) do not exist to characterize the status of the manufacturing readiness of developmental systems. Best industry and government practices have shown that most significant cycle time reductions result when technology performance and manufacturing processes are matured concurrently. A Transition Working Group, comprised of representatives from the Military Services, Defense Logistics Agency (DLA), Missile Defense Agency (MDA), and industry, recently addressed the issue of rapid, affordable transition of technology to acquisition and generated a set of definitions and descriptions for Manufacturing Readiness Levels (MRLs). MRLs are measures used to assess the system engineering/design process and maturity of a technology's associated manufacturing processes. This appendix provides the definitions and descriptions, with a view toward improving awareness of the MRL concept and for use of the MRLs during system research and development (R&D).

Table G-1 shows the proposed MRLs. Nine levels of MRLs were used for convenience when comparing technology readiness and manufacturing readiness. For example, an

Table G-1. MRL Definitions and Descriptions

MRL	Definition	Description	Acquisition Phase
1	NA		
2	NA		
3	Manufacturing concepts identified	Identification of current manufacturing concepts or producibility needs based on laboratory studies.	Pre-concept refinement
4	Laboratory manufacturing processes identified	Key processes identified and assessed in laboratory. Risk mitigation strategies identified to address manufacturing/producibility shortfalls. Preliminary Cost as an Independent Variable (CAIV) targets set and cost drivers identified.	Concept refinement leading to a Milestone A decision
5	Manufacturing process development	Trade studies and laboratory experiments result in development of key manufacturing processes and initial sigma levels needed to satisfy CAIV targets. Preliminary manufacturing assembly sequences identified. Process, tooling, inspection, and test equipment in development. Significant engineering and design changes. Quality and reliability levels not yet established. Tooling and machines demonstrated in the laboratory. Physical and functional interfaces have not been completely defined.	Technology Development (TD)
6	Critical manufacturing processes demonstrated	Critical manufacturing processes initially demonstrated for the relevant environment (laboratory or simulated operational environment). Initial goals established for yields. Process and tooling generally mature. Frequent design changes still occur. Investments in machining and tooling identified. Quality and reliability levels identified. Design to cost goals identified.	TD, leading to a Milestone B decision
7	Prototype manufacturing system	Prototype system built based on mature tooling. Initial sigma levels established, based on yields and quality data from laboratory or simulations. Design changes decrease significantly. Process tooling and inspection and test equipment demonstrated in pre-production environment. Manufacturing processes well understood. CAIV and design to cost goals validated.	System Development and Demonstration (SDD)
8	Manufacturing process maturity demonstration	Manufacturing processes demonstrate acceptable yield and producibility levels for pilot line, low rate initial production (LRIP), or similar item production. All design requirements satisfied. Manufacturing processes well understood and controlled to 4-sigma or appropriate quality level. Minimal investment in machine and tooling (should have completed demonstration in at least a low-rate production environment). Cost estimates less than 125 percent of cost goals (e.g., design-to-cost and CAIV goals met for LRIP).	SDD, leading to a Milestone C decision and LRIP
9	Manufacturing processes proven	Manufacturing line operating at desired sigma or similar quality level. Stable design and production. All manufacturing processes controlled to 6-sigma or appropriate quality level. Cost estimates less than 110 percent of cost goals or meet cost goals (e.g., CAIV and design-to-cost goals met).	Production, deployment, and support

MRL of 6 or 7 is appropriate for entry to milestone B and assessment during System Development and Demonstration (SDD), just as a TRL of 6 or 7 is appropriate for Milestone B and SDD. MRLs 1 and 2, because the relative immaturity of technology at TRL 1 and 2, are not seen as meaningful for assessing manufacturing readiness.

The MRL definitions are based on the integration of existing industry, government agency, and technical coalition standards and recommendations to address producibility concerns earlier in the development phase (e.g., Engineering & Manufacturing Readiness Levels being used by the Milestone Decision Authority (MDA)]. They can be tailored to apply at the component, subsystem, and system levels and are a framework with specific criteria and metrics to capture the design and manufacturing knowledge for product development, demonstration, and production. The definitions support assessments of the maturity of the design, related materials, tooling, test equipment, manufacturing processes, quality and reliability levels, and key characteristics necessary for producible and reliable products.

ACRONYMS AND ABBREVIATIONS FOR APPENDIX G

CAIV	Cost as an Independent Variable
DLA	Defense Logistics Agency
DoD	Department of Defense
DoDD	Department of Defense Directive
DoDI	Department of Defense Instruction
LRIP	low rate initial production
MDA	Missile Defense Agency
MRL	Manufacturing Readiness Level
R&D	research and development
SDD	System Development and Demonstration
TD	Technology Development
TRL	Technology Readiness Level

APPENDIX H
ELEMENTS OF TECHNOLOGY TRANSITION AGREEMENT

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The following elements should be considered for inclusion in a technology agreement between an acquisition program, the intended receiver of a technology or capability development, and a science and technology activity, the developer and provider of the technology. Not every one of these elements is appropriate for every agreement, but each agreement should have considered these for inclusion.

Agreements, to be effective, must be reviewed periodically with both S&T management and program office management representatives participating. These reviews should address technical progress and future directions.

Elements to be provided by the Program Office:

a. **Target Acquisition Program.** A brief description of the acquisition program intended to receive the technology that is to be transitioned. Include major program objectives, current phase of acquisition life cycle, and projected initial operational capability date.

b. **Program Manager/Project Officer.** Program manager and individual in program office responsible for day-to-day management with contact information.

c. **Acquisition Program Technology Need.** Brief description of the benefit that this technology will bring to the acquisition program, or need satisfied. Where possible, relate benefit to ORD, KPP, etc. Include need dates for specific capabilities.

d. **Integration Strategy.** Describe the process for integrating the technology into the acquisition program. Include elements of acquisition strategy – evolutionary acquisition, block upgrade, etc., as well as required contractor to contractor agreements

Elements to be provided by S&T Activity

a. **Description of Technology or Capability to be Delivered.** Brief description of what the S&T activity intends to develop for transition to the acquisition program. Include capability delivery dates.

b. **Technology Manager.** Individual designated by the S&T activity to be the coordinator and day-to-day manager of the development of the needed technology.

c. **Current Status of Technology.**

1. **Status Summary.** Summarize current state of development. Identify primary areas where additional development is required. Provide estimate of current TRL.

2. **Risk Analysis.** Major areas of risk, prioritized, with planned mitigation activities. Include technical (e.g., producibility, affordability, sustainability) cost, and schedule risks.

d. **Technology Development Strategy**. Outline approach planned. Efforts required beyond those currently underway; integration plans if multiple projects are planned. Planned ATD or ACTD developments, if applicable

e. **Key Technical Measures of Readiness to Transition.** Identify the key parameters or attributes that will be used to measure whether or not the technology development effort is proceeding appropriately. Include parameter to be tracked, current state, interim progress estimates, and final objective. Technology Readiness Levels are a measure of technical maturity and can be used to assess readiness to transition.

f. **Program Plan.** Show major activities/efforts comprised by the technology development activity with milestones.

Signatures. Technology transition agreements should be signed as required to commit the participating organizations to the plan outlined in the agreement. The program manager(s) of the acquisition program(s) involved and the S&T project manager, should sign.

- SAMPLE -

TECHNOLOGY TRANSITION AGREEMENT

Basic Transition Agreement

1. **Description of Technology or Capability to be Delivered.**

2. **Target Acquisition Program.**

3. **Acquisition Program Technology Need**

4. **Integration Strategy**

5. **Program Manager/Project Officer**

6. **Technology Manager**

Technical Details and Programmatics

1. **Technology – Current Status**

   a. **Summary – Status**

   b. **Risk Analysis**

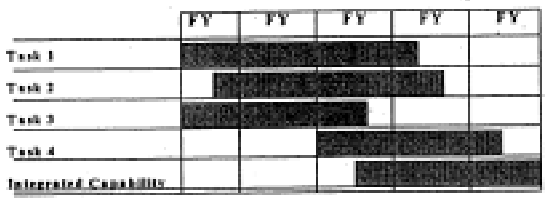
Top Risks	Brief Description	Mitigation Strategy

2. **Technology Development Strategy.**

3. **Key Measures of Transition Readiness**

Attribute/Parameter	Current	Interim (w/Est Date)	Final Objective

4. **Program Plan**



SIGNATURES:

Acquisition PM

S&T Project Manager

ACRONYMS AND ABBREVIATIONS FOR APPENDIX H

ACTD	Advanced Concept Technology Demonstration
ATD	Advanced Technology Demonstration
FY	Fiscal Year
KPP	key performance parameter
ORD	Operational Requirements Document
S&T	science and technology
TRL	Technology Readiness Level